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# ALBANIA LAWS AND REGULATIONS AFFECTING COMMERCIAL SUPPLY OF MODERN CONTRACEPTIVES: ANALYSIS AND RECOMMENDATIONS

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This publication was produced for review by the United States Agency for International Development. It was prepared by Pamela Riley and Kristen Maddock for the Private Sector Partnerships-*One* project.



**PSP-*One***

PRIVATE SECTOR PARTNERSHIPS FOR BETTER HEALTH

## **Country Report**

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## **DISCLAIMER**

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# ACRONYMS

<b>ACCESS</b>	Access to Clinical and Community Maternal, Neonatal, and Women’s Health Services
<b>ACPD</b>	Albania Center for Population and Development
<b>C-Change</b>	Communication for Change
<b>CIF</b>	Cost, Insurance, Freight
<b>COM</b>	Council of Ministers
<b>CSO</b>	Civil Society Organization
<b>DFID</b>	Department for International Development, UK
<b>DHS</b>	Demographic and Health Survey
<b>DNC</b>	Drug Nomenclature Commission
<b>DPC</b>	Drug Pricing Commission
<b>EU</b>	European Union
<b>FP</b>	Family Planning
<b>FPRA</b>	Family Planning Regional Activity
<b>HII</b>	Health Insurance Institute
<b>IPH</b>	Institute for Public Health
<b>IPPF</b>	International Planned Parenthood Federation
<b>IUD</b>	Intrauterine device
<b>JSI</b>	John Snow, Inc.
<b>KfW</b>	<i>Kreditanstalt für Wiederaufbau</i>
<b>MCH</b>	Maternal and Child Health
<b>MOF</b>	Ministry of Finance
<b>MOH</b>	Ministry of Health
<b>NCQSAHI</b>	National Center of Quality, Safety, and Accreditation of Health Institutions
<b>NCDC</b>	National Center for Drug Control
<b>NGO</b>	Nongovernmental Organization
<b>OTC</b>	Over the Counter
<b>PSP-One</b>	USAID Private Sector Partnerships-One Project
<b>RH</b>	Reproductive Health
<b>RH/FP</b>	Reproductive Health/Family Planning
<b>SMO</b>	Social Marketing Organization
<b>UNFPA</b>	United Nations Population Fund
<b>USAID</b>	United States Agency for International Development
<b>VAT</b>	Value-added Tax
<b>WHO</b>	World Health Organization



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# EXECUTIVE SUMMARY

The USAID Mission in Albania requested the Private Sector Partnership-*One* (PSP-*One*) project to assess Albania's laws and regulations applicable to the private supply of modern contraceptives. The objectives were: 1) to catalogue existing laws, policies, and decisions that affect availability and affordability of contraceptives in Albania and identify barriers, gaps, inconsistencies, and recommendations; and 2) to identify and support local nongovernmental organizations (NGOs) that might serve as champions for the recommended changes.

Following extensive desk research and interviews with public and private sector stakeholders familiar with Albania health sector regulation, PSP-*One* located more than 24 laws and decisions relevant to the private sector supply of contraceptives (translated copies are attached in Annex C). Topics areas included: social marketing policy, customs and import, registration, taxation, pricing, reimbursement, promotion, and prescribing. For each topic, gaps and recommendations for policy changes are provided.

Main findings and recommendations:

**Access to information:** Albania lacks a routine process for publishing ministerial decisions, resulting in confusion and conflict among government staff about existing rules and inconsistent enforcement. These problems are exacerbated by frequent changes in agency leadership and staff, resulting in misinformation by those in charge of implementing the law. Policies requiring automatic posting to a search-friendly web site of all agency decisions throughout the government would improve efficiency, facilitate stakeholder collaboration, and enhance information available for decision making.

**Social marketing:** A significant policy impediment to a stronger private sector market for contraceptives is the lack of clarity around the legal rights and obligations of Albania's social marketing organization NESMARK. NESMARK's ambiguous regulatory status has resulted in conflicting requirements, disruptions in supply, and competitor confusion. Social marketing organizations need clearly defined structure and regulatory status, with alignment among donors and the Ministry of Health (MOH), and effective communications to commercial suppliers.

**Customs and registration:** Customs, import, and registration requirements for commercial suppliers are basically sound, with reasonable requirements for documentation, processing timeframes, and fees. Recent changes, adopted in October 2008 to streamline drug import approvals, were quickly withdrawn by the MOH, following implementation problems leading to shipments being held at Customs. Future efforts to reform import processes requires better long-term planning, input from affected parties including Custom Department staff, and training and stakeholder communication to maintain a predictable and orderly process prior to promulgation.

**Pricing and reimbursement:** To improve affordability of contraceptives, hormonal pills should be included on the Drug Reimbursement List approved by the Drug Commission for inclusion in the Health Insurance Institute's national insurance scheme. Other policy changes to support lower contraceptive prices include use of reference pricing from other countries to compare manufacturer's stated costs, providing more flexibility on profit margins across the supply chain, and communication of approved price ranges for socially marketed drugs. Condoms and other medical devices should be exempted from the 20 percent value-added tax.

**Promoting and prescribing:** Policies requiring prescriptions are not enforced, with patients routinely acquiring “prescription drugs,” including hormonal pills, without prescriptions. Prior to stepping up prescription enforcement, improvements are needed in prescribing practices of doctors who do not comply with World Health Organization criteria for prescribing practices. There is little incentive for patients to utilize doctor channels for contraceptive prescriptions, given that pharmacists dispense drugs without prescriptions, and anecdotal evidence suggests that doctors may limit access. Policies prohibiting advertising of prescription drugs directly to consumers are weakly enforced and should be strengthened by adoption of a Professional Code of Ethics in Drug Promotion.

To take this analysis to the next stage, the Albanian Center for Population and Development (ACPD) has agreed to review and consider incorporating the key recommendations of this report as part of their advocacy activities to improve sexual and reproductive health in Albania. The ACPD is an Albanian NGO, an affiliate of the International Planned Parenthood Federation, currently implementing a five-year strategic plan funded by the U.K. Department for International Development. The ACPD’s strategic objectives include developing an Advocacy Coalition to hold the government accountable for implementing current and proposed reproductive health policies. The recommendations in this report fit with the ACPD’s multi-pronged advocacy approach, which includes development of strategies to improve policies in the areas of adolescent health care, maternal and child health, and family planning. Recommended priority changes include advocacy for a strengthened social marketing sector, and support for oral contraceptives on the Drug Reimbursement List to make them eligible for national health insurance coverage.

# INTRODUCTION AND OVERVIEW

A robust private sector supply of reproductive health (RH) products helps to ensure access to and availability of choice and quality of contraceptive commodities. Government policies and laws can create an enabling environment that facilitate competitive supply or, conversely, can place undue burdens on importers, manufacturers, distributors, and suppliers of essential RH commodities (Hare et al., 2004). This paper looks at Albania's legislative and regulatory policies governing the import and sale of modern contraceptives, and identifies policy barriers to improved contraceptive availability. It also provides direction for local advocacy efforts to implement the changes needed to promote choice and access to contraceptives for all Albanians.

This report is divided into three sections. **Section 1** contains background, objectives, methodology, and findings. **Section 2** summarizes specific laws, gaps, and recommendations related to the following policy areas: Social Marketing, Customs/Import, Drug Registration, Reimbursement, Pricing, Promotion, Prescribing, and Taxes and Fees. **Section 3** addresses the advocacy strategy to promote stronger RH/FP policy framework.





# I. BACKGROUND, OBJECTIVES, AND METHODOLOGY

## I.1 BACKGROUND

The Private Sector Partnership-*One* (PSP-*One*) project conducted an assessment of the private contraceptive market in Albania in 2008, consistent with objectives to increase the private sector's provision of high-quality RH and family planning (FP) and other health products and services. In that assessment, PSP-*One* identified a number of regulatory issues that have the potential to curb private sector provision of contraceptives (Holley, 2008). These included rules related to registration, importation, distribution, retail sale, promotion, pricing, and taxation of drugs and medical devices.

The USAID Mission in Albania requested PSP-*One* to provide this follow-up technical assistance to identify specific gaps and recommendations in the laws with an impact on a robust supply of modern contraceptives. This PSP-*One* technical assistance is being funded by the Europe & Eurasia Bureau's Family Planning Regional Activity (EE FPRA), with the expectation that successful policy reforms in Albania will have relevance for other countries in the region sharing the "intermediate"-level market conditions for private sector development.

**Overview of Albania's legal framework:** Albania is a Parliamentary Republic, with separation of power between the legislative, executive, and judicial branches. Parliament represents the legislative branch; all laws must be in compliance with the Constitution (adopted in 1998). International treaties and conventions ratified by Parliament prevail in the event there is inconsistency with Albanian legislation.

The executive branch consists of the President as Chief of State, and the Council of Ministers, who are appointed and headed by the Prime Minister. The Council of Ministers introduces draft laws to Parliament, and issues acts, decisions, instructions, regulations, and orders to implement laws approved by Parliament. Each ministry is also authorized to issue instructions, regulations, and orders within their areas of control.

**Overview of Albania's pharmaceutical laws:** The pharmaceutical sector was privatized in the 1990s. Many individual laws govern the sale of pharmaceuticals, but a framework Law on Drugs adopted in 2004 establishes key components including drug registration, import and export permits, wholesale and retail licenses, and pricing and advertising. More than 50 articles of this Law on Drugs required further action by Council of Ministers or Minister of Health to implement, but rules for a number of articles have never been adopted.

**Overview of Albania's RH policy:** In 2002, Albania adopted a Law on Reproductive Health (Law 8875), which establishes that all individuals and couples have the right to benefit from the use of secure, affordable, and acceptable methods of family planning (FP), according to their choice. Under the leadership of the Ministry of Health (MOH), a National Contraceptive Security Strategy was published in 2003 by the National Reproductive Health Commission. Contraceptive security was defined as a guaranteed long-term supply of quality contraceptives for every Albanian who wants them. The Commission has since been disbanded and replaced by a Reproductive Health Council within the MOH. The RH Council is chaired by the Deputy Minister of Health, and consists of 11 members including

representatives of other government departments, donors, and clinical experts. There are four committees including a Contraceptive Security Working Group and a RH Strategy Working Group. The RH Council serves as a national focal point for the development of RH policies and is currently drafting a new Reproductive Health Strategy to provide a framework for the future.

## 1.2 OBJECTIVES

There were two objectives for this policy review:

The first objective was to catalogue or “map” existing laws, sub-laws, regulations, decisions, and amendments that affect availability and affordability of contraceptives in Albania, and recommend areas for change. Laws and regulations in Albania are not published and searchable in a comprehensive, systematic way. An inventory of existing rulings was needed to create a shared understanding of current policies and their implementation. Recommendations for policy changes are based upon identified gaps, inconsistencies, and barriers.

The second objective was to identify local nongovernmental organizations (NGOs) that might serve as champions for policy changes recommended by the regulatory assessment, and that could take a leadership role in advocating for FP objectives in Albania. Recommendations in this report are intended to guide activities of civil society organizations (CSOs) working toward sustainable platform to promote change for FP policies.

## 1.3 ISSUES OUTSIDE THE SCOPE OF THIS REPORT: HEALTH CARE REFORM AND FP DEMAND

**Broad health system reform:** The Albanian government is currently working to reform its overall health care system, with changes in the way health care is financed, delivered, and organized through the public sector. A broad framework Law on Healthcare has been drafted with new roles and responsibilities for the MOH, Health Insurance Institute (HII), and Institute of Public Health (IPH), but many factors are still in flux. The World Bank and other donors are providing assistance in priority areas for reform including improved resource allocation among primary and secondary care facilities and improved quality of care. While these changes will impact the intersection of public and private sector services, this paper does not address these broader health system strengthening efforts.

**Low demand for contraceptives:** The focus of this analysis is only on regulatory and legal impediments to a more robust contraceptive market. Many other factors influence contraceptive supply, most notably demand. Stakeholders from both the commercial and donor communities were in agreement that low demand for contraceptives, not regulatory policy, is the most significant barrier to a more active commercial supply in Albania. The reasons for low demand for contraceptives have been documented in various market assessments, which point to a conservative culture, lack of consumer awareness about safety and effectiveness, and outdated medical skills and prescribing practices of doctors (John Snow, Inc. [JSI], 2007; Holley, 2008). Concurrent efforts underway to stimulate demand include USAID projects Family Planning Service, Expansion and Technical Support (SEATS II), Albania Child Survival Project (ACSP), Communication for Change (C-Change), and Access to Clinical and Community Maternal, Neonatal and Women’s Health Services (ACCESS), as well as the United Nations Population Fund (UNFPA) campaigns and efforts through the Albanian IPH. This report does not address policies targeting demand-side changes but rather focuses only on supply.

## 1.4 METHODOLOGY

**Literature Review:** Through extensive desk research, PSP-One located numerous overview documents providing context for Albania's legal framework and overall contraceptive market. A translator helped to identify some relevant regulations on the MOH Web site. The Official Gazette of Albania publishes laws adopted by Parliament, but they are not searchable by topic, making it difficult to locate related laws. The majority of decisions by agencies such as the MOH were located only through help of knowledgeable staff.

**Stakeholder Interviews:** PSP-One scheduled meetings with relevant government officials to gain permission to work with their legal and policy staff to identify relevant rulings. Additional meetings were scheduled with regulatory staff of companies and other stakeholders operating in this sector to learn more about processes, costs, and timeframes for compliance. A list of sources is provided in Annex A.

**Translation:** Very few of the laws and decisions affecting pharmaceutical supply in Albania were available in English. Those considered to be most relevant were translated and are attached in Annex C. A large number of the orders relevant to this research were provided by the MOH Department of Pharmacy in a bound collection that was not circulated or available to many other stakeholders.

## 1.5 SUMMARY OF FINDINGS

**Albania lacks a systematic process for publication of ministerial orders and decisions.** All laws adopted Parliament are published in the Official Gazette, but many sub-legal acts issued by the Council of Ministers and individual ministries are not. There is an Official Publication Centre operated by the Ministry of Justice, but there is no standard practice for forwarding, posting, indexing, and updating ministerial decisions. As a result, research for this report required contacts with individual departments within the MOH, HII, and National Center for Drug Control (NCDC) who were able to identify and provide copies of relevant decisions. Weak dissemination practices contribute to regulatory delays and inconsistent compliance with some provisions. This was particularly evident in recent changes to import procedures, now withdrawn.

**The overall legal framework for the import, distribution, and sale of contraceptives is basically sound.** There is a comprehensive process for registration, inspection, and sale through licensed private pharmacies. Manufacturers and wholesalers active in the sale of contraceptives consistently cited low consumer demand as the primary barrier to a broader range of contraceptive products in Albania. Timeframes for processing shipments through customs were described as average for the region, with new fast-track procedures for drugs sold in selected developed markets likely to shorten average approval cycles. Customs fees and tariffs were not considered to be onerous.

**The social marketing sector needs to be better rationalized.** Albania's current social marketing organization lacks clear legal status, with divergent stakeholder views about the "legality" of an NGO with a social mission generating revenues from product sales. Delays at Customs tied to conflicts over import authorizations, pricing, packaging, and taxes have led to stock-outs and inconsistent rulings. The decline of an active social marketing sector will significantly decrease the affordable contraceptives to Albania consumers (Tien and Rao, 2009).

**Additional weaknesses in policies governing contraceptive supply relate to the lack of criteria for some areas of oversight.** Two advisory bodies, the Drug Nomenclature Commission (DNC) and the Drug Pricing Commission (DPC), lack defined standards for decision making, resulting in pro-forma approvals. Promotional rules governing advertising of prescription drugs to consumers should

be strengthened through adoption of an industry and MOH-endorsed Code of Ethics. Doctors lack standard clinical treatment protocols and prescribing guidelines.

**Pricing, reimbursement, and tax policies should be revised to increase affordability of contraceptives.** Pricing criteria should include requirements for reference pricing of manufacturers' stated costs, and there should be more flexibility for suppliers to adjust profit margins across the supply chain. Condoms and other medical devices should be exempted from the 20 percent value-added tax (VAT). Hormonal pills should be included on the Drug Reimbursement List for inclusion in the HII national insurance scheme.

**The Albania Center for Population and Development (ACPD), a local NGO, should incorporate the recommendations of this report into its RH strategy.** Albania has historically lacked a champion willing to keep FP a priority on the national health agenda, and to hold the government accountable for implementing RH policies. The ACPD appears well-positioned to play this role with the recent launch of a well-funded and detailed five-year plan to strengthen civil society advocacy for sexual rights and RH.

## **2. COMPENDIUM OF LAWS, DECISIONS, AND REGULATIONS RELEVANT TO SUPPLY OF MODERN CONTRACEPTIVES, WITH ANALYSIS AND RECOMMENDATIONS**

This section catalogues, summarizes, and analyzes current laws, sub-laws, orders, and policies governing the commercial production, distribution, and sale of contraceptives in Albania. There is no systematic practice for publishing all ministerial decisions in a single place, making it time-consuming and challenging to identify and locate the relevant documents. A list of all laws and decisions identified is attached in Annex B, but this likely has a number of gaps, and will rapidly become outdated. A number of other laws are referenced that were not translated or attached, such as the Customs Code; these are marked “not appended to this report.” The current ad hoc dissemination process weakens the rule of law and creates procedures vulnerable to inconsistent application or favoritism. Clearly, Albania would benefit from a centralized publication system, searchable by subject area, law number, date, and source.

The section is divided into eight topic areas. For each topic, a list of relevant Parliament-approved laws and ministerial orders are listed and described, with a discussion of recommended changes.

2.1 Social marketing

2.2 Registration

2.3 Customs and import

2.4 Pricing

2.5 Reimbursement

2.6 Taxes and tariffs

2.7 Prescribing

2.8 Promotion

## 2.1 SOCIAL MARKETING

**TABLE 2.1 SOCIAL MARKETING LAWS AND DECISIONS**

Key Laws & Decisions (Date)	Description
NESMARK Agreement (1997)	Financing and Project Agreement between KfW, MOH, and NESMARK; expires Dec. 30, 2009
NESMARK Foundation Charter	Establishes NESMARK's status and obligations as a foundation (not appended to this report)
Law 8788 (May 7, 2001)	On not-for-profit organizations, imposing a 10% tax on operations (not appended to this report)
Law 8875 (Apr 4, 2002)	Framework law on RH, establishing rights of individuals to make decision related to reproduction without discrimination, obligation, or violation
MOH decision on NESMARK price margins	Adjusted permitted margins to 44% for emergency contraceptives, 41% for injectables (not available)
MOH RH Committee Strategy 2009	RH Committee collaborative effort to establish long-term goals for reproductive health/family planning (RH/FP) (not appended to this report)
<b>GAPS/RECOMMENDATIONS</b>	
<ul style="list-style-type: none"> <li>The current social marketing program in Albania lacks clear objectives, limiting its ability to fill gaps in the contraceptive market. An effective social marketing organization (SMO) needs clear legal status to guide its products, pricing, and promotion.</li> <li>An updated market segmentation study using forthcoming 2009 Demographic and Health Survey data should be undertaken to improve access to contraceptives across the market spectrum. The RH Council should articulate strategies and objectives for reaching unserved market segments, endorsed by the MOH.</li> </ul>	
<p><b>Proposed changes:</b> Following endorsement of market segmentation strategy, the MOH should align legal status and structure of SMO to meet national objectives.</p>	

## DISCUSSION

**Background:** Albania needs new policies to define and endorse the role of social marketing as a methodology to increase access, awareness, and availability of needed contraceptive products. Social marketing is a well-established mechanism for stimulating demand for health products and services, and providing low-cost options for targeted segments of the population who might not otherwise have access. Currently, Albania's social marketing sector consists of one social marketing organization (SMO), NESMARK, the largest supplier of contraceptives in the country. The establishment of NESMARK in 1997 was intended to serve the large market segment in Albania who do not avail themselves of free public contraceptives and cannot afford commercially priced alternatives. It is funded by KfW under a contract due to expire at the end of 2009.

Extensive analyses of NESMARK's history, strengths, weaknesses and future options have been covered in previous studies and reports (Dowling, 2006; JSI, 2007; Holley, 2008; Tien and Rao, 2009). The purpose of this report is to highlight how Albania policies, laws, and rules have created ambiguity for the social marketing sector. This ambiguity has resulted in a reduced supply of affordable contraceptives.

Specific policy disputes include:

**Product sales:** Bayer-Schering, a major commercial supplier in the market, believes that as a NGO with a social mission, NESMARK is breaking the law by selling products as a nonprofit. “Social marketing organizations should be limited to building consumer awareness and knowledge.”

**Branding:** Commercial suppliers argue that given its subsidization, it is unfair for NESMARK to market specific brands rather than promote the category. Distributor OES reports that NESMARK is taking share from commercial providers that must rely solely on profits to procure, advertise, and sell competing brands.

**Pricing:** Following adoption of the price margin decision for all pharmaceuticals in 2005, NESMARK entered into protracted negotiations with the government, arguing that fixed margins on its very low costs, insurance, and freight (CIF) did not permit sufficient revenues for operations. New margins were eventually agreed upon, but NESMARK’s emergency contraceptives and contraceptive pills were off the market for a year. NESMARK believes that lack of pricing flexibility has hurt sales for consumers who equate low price with low quality.

**Import and packaging:** NESMARK’s oral contraceptive Sigoral was off the market for more than a year because the packaging from the manufacturer did not include a government-approved label, and there were lengthy negotiations to calculate the payment for adding required stickers to the packages. NESMARK reports that market share has declined as pharmacists avoid stocking based on its perceived unreliable availability.

*“It has never been made clear to me whether NESMARK is considered an importer, a wholesaler, a distributor, a retailer, or something else. Which rules do I follow?”*  
*Executive Director, NESMARK, April 28, 2009*

**Legal status:** It is NESMARK’s view that, because it is governed by an agreement between the governments of Germany and Albania to fulfill an approved mission, the agreement should take precedence over local laws related to import, taxation, and marketing. Albanian legal experts note that the NESMARK Agreement was never ratified by Parliament, which would be required for it to become controlling law. Confusion has resulted. For example, in 2005 NESMARK was told by the then Directorate of Pharmaceuticals that they would need to obtain a Permission of Import, and they invested significant effort to comply with requirements such as having a qualified pharmacist on staff, instituting specific warehousing and distribution functions, and obtaining other licenses. The MOH later told them that, as an SMO, they were governed by different provisions, and such requirements did not apply.

**Taxation:** Ambiguous contract language seems to provide for the Ministry of Finance (MOF) to bear public charges accrued outside of Germany in connection with the agreement, such as taxes, so NESMARK had been receiving reimbursements for the VAT. For reasons unclear to NESMARK, the reimbursements abruptly ended in 2004. NESMARK now pays the VAT and a 10 percent income tax as an NGO, but is not clear what its legal rights are.

These examples underscore the need to strengthen Albania’s current approach to social marketing with a new set of policies designed to grow an effectively segmented market in a more coordinated fashion.

Recent market research confirms the ongoing need for effective social marketing programs to address underserved segments of the market. The contraceptive prevalence rate is low, the small size of Albanian market limits the interest of commercial investment, and commercial prices are out of reach for many Albanians (Dowling, 2006; JSI, 2007; Holley, 2008). NESMARK retains considerable market share of condoms, oral pills and emergency contraceptives (Tien and Rao, 2009). A policy framework is needed to articulate social marketing FP goals, to facilitate design of appropriate rules protected from regulatory limbo, and to protect fair competition and product quality.

**Revising Albania's social marketing policies:** In the most recent Contraceptive Security Analysis, 2009-2013, recommendations underscored the need for policy decisions to implement proposed changes in market shares between the public, commercial, and social marketing sectors. Specific questions were posed to the MOH regarding its goals for the contraceptive prevalence rate, level of available funding, and desired role for donors as critical first steps in promoting a secure supply of contraceptives (Tien and Rao, 2009). Building on these recommendations, two steps are needed to rationalize and facilitate contraceptive use. These recommendations are applicable whether NESMARK remains the active SMO or a new entity is developed to replace it.

Step 1. The government should establish specific objectives for contraceptive prevalence to rationalize the role for social marketing.

Transparent and prioritized objectives from the government are needed for collaboration between the public and private sectors for rationale allocation of resources. MOH priorities should drive the structure and activities of the social marketing sector, which may range from improving access for the poor, reducing public sector share, or undertaking awareness-raising activities for RH/FP to improve targeting of donor funding.

To inform these objectives, the Albania's 2006 Market Segmentation Analysis should be updated with new Demographic and Health Survey (DHS) data, due to be published shortly, replacing the 2002 DHS. Market segmentation analyses inform equitable and efficient allocation of resources. Ideally, the DHS data should be supplemented with additional research into willingness to pay, attitudes toward FP, sources of influence, and other psycho-social factors that influence use of contraceptives. RH Council leadership in the design and implementation of new market segmentation strategies will facilitate representation and coordination among the commercial, donor, and public sector representatives.

Once the government identifies market gaps not served by the public or commercial sectors, social marketing objectives should be established. A range of social marketing approaches exist, from a donor-funded NGO model aimed primarily at serving hard-to-reach groups, a manufacturer's model aimed primarily at introducing lower-priced sustainable brands into the market, or a hybrid that spans the two (Armand, 2003).

Other factors influenced by contraceptive prevalence targets include:

**Promotion:** Tensions typically arise in markets over whether SMOs that provide donor-subsidized products should be limited to building category awareness and behavior change, in order not to lure customers from profitable commercial sales. Others argue that consumers need brand marketing to generate sales for SMOs, which can then subsidize consumer education campaigns to attract non-users unreached by public or commercial providers. Policies guiding the social marketing sector should offer the underlying rationale for socially marketed products tied to explicit market objectives.



**Pricing:** NESMARK has suffered from the absence of an established policy for pricing of social marketing brands, resulting in protracted negotiations and market interruptions. NESMARK has argued that higher margins for subsidized products are needed to provide sufficient revenues for long-term sustainability. Some pricing officials at MOH argued for lower margins in light of ongoing subsidies and claims of “excessive profits.” Pricing policies should be set in collaboration between MOH and donors/SMOs based upon updated market data including data on the size of segments in need of price discounts, and on ability and willingness to pay.

**Place:** The proposed updated market segmentation analysis should identify the specific segments where SMO products are most needed, such as vulnerable groups, or medium-density cities with fewer commercial suppliers than Tirana, or users of a certain income level. Public-private agreements between the SMO and local primary care facilities may create logistics partnerships or referral mechanisms to enforce targeting to the priority segments.

Step 2: SMO legal rights and obligations should be clarified.

If a social marketing program is to be nurtured in Albania, either through NESMARK or a new organization model, a new set of policies must clear the way, starting with clarity regarding SMO legal rights and obligations. A primary component of successful social marketing programs is institutional sustainability, including clear legal status (O’Sullivan et al., 2007).

Like many SMOs that begin as donor projects, NESMARK’s combined foundation/ commercial activities gives it ambiguous regulatory status, leaving it vulnerable to regulatory penalties, conflicting priorities, market confusion, and poorly allocated resources (O’Sullivan et al., 2007). Enforcement of the NESMARK contractual agreement is left to interpretation by the MOH, leaving NESMARK vulnerable to changes based on personal relationships and outside influences.

There are a number of models to explore regarding the optimal SMO structure, depending upon the government’s long-term objectives. For example, a social marketing organization can be divided into complementary divisions, one with the social functions of a humanitarian nonprofit and the other with a commercial function, creating different organizational cultures. Separating the commercial and social functions of an SMO can enhance sustainability efforts on the commercial side while providing clearer focus to the social activities.

In Romania, for example, a single SMO was divided into complementary divisions, one with the social functions of a humanitarian nonprofit and the other with a commercial function, creating different organizational cultures. This regulatory structure thus avoided the pitfalls and regulatory risks associated with maintaining a nonprofit legal identity while becoming more aggressive in pricing and marketing its products. Separating the commercial and social functions of an SMO can enhance sustainability efforts on the commercial side while providing clearer focus to the social activities. The commercial entity pays customs, and value-added and income taxes to the Romanian government, but the systematic donation of profits to Population Services International Romania helps to reduce this tax burden (O’Sullivan et al., 2007).

## 2.2 REGISTRATION

**TABLE 2.2 REGISTRATION LAWS AND DECISIONS**

Key Laws & Decisions (Date)	Description
MOH 525 (1998)	Establishes DNC
Law 9323 (Nov 25, 2004)	Primary law on drugs; defines the rules of production, importation, exportation, trading, prescribing, usage, quality control, and inspection of actions related to drugs
MOH Regulation 1588 (May 25, 2005)	Regulation on registration; implements Law 9323, including information needed with application, and procedures for renewal and re-registration (not appended to this report, subsumed by MOH Regulation 73 below)
Law 9523 (Apr 26, 2006)	Amends 9323, adds permitted countries of origin and penalties for violations
MOH Order 256 (July 10, 2006)	Authorizes import of unregistered drugs in certain circumstances
Law 10008 (Oct 27, 2008)	Amends 9323; adds fast-track registration, transfers authority over pharmacies and wholesalers to IPH regional offices, and creates new process at Customs
MOH Regulation 73 (March 3, 2009)	Amends regulation on registration 1588 by adding Chapter III to implement fast-track registration process
<p><b>GAPS/RECOMMENDATIONS</b></p> <ul style="list-style-type: none"> <li>• DNC role should be strengthened with specific criteria and processes for drug review and approval, to ensure technical expertise and more transparency in decision making.</li> <li>• Law limits registration of drugs to those previously approved in specific developed markets, limiting ability to import lower-priced generics from countries not on the list. Given the small size of the Albanian market, and reasonable number of lower-priced generics registered in the United States or European Union, no change is recommended to these registration restrictions.</li> <li>• Donated products are not required to be registered, which creates potential for inconsistent treatment, concerns about quality, and confusion about getting drugs through Customs. All these factors pose risk of delay. Recommend removing exemption from registration requirement but provide other ways to recognize donor generosity such as waiving registration fees and fast-tracking applications.</li> </ul> <p><b>Proposed changes:</b> Per Article 12 of Law on Drugs 9323, the MOH should issue a directive establishing the function of the DNC, including criteria for evaluating and approving drug applications.</p>	

## DISCUSSION

Albania ensures the quality of all medicines available in the country, including RH commodities, through registration procedures intended to protect the public from unsafe, mislabeled, or counterfeit medicines. The NCDC is responsible for drug registration and inspection in procedures set forth in detailed regulations (MOH Order 1588, amended).

The process begins with the filing of an application by an authorized representative for the manufacturer, containing information such as certifications of good manufacturing practice, registration certificates from other markets, product characteristics, and clinical documentation. NCDC specialists conduct testing if required, provide random inspections, and require reporting of adverse events. After

the NCDC completes its review, the application is forwarded to the DNC for its review and recommendation. The application is then sent to the MOH for final decision and issuance of a registration and marketing approval for the Albanian market. There is no avenue of appeal outside of the MOH if drugs are rejected or de-registered.

The registration process was strengthened by amendments to the original law that protected “first to file” registration of active pharmaceutical ingredients of a drug. Under current law, there is no monopoly right given to registrants of an active ingredient, which has increased price and product competition. The NCDC director reports that Albania now has more than 5,600 registered drugs, from 360 companies, through 90 importers, demonstrating its open and competitive approach.

This registration process in Albania is relatively well functioning with commercial suppliers reporting reasonable timeframes and processes, when benchmarked against other countries in the region. Registration fees of approximately 800 Euro per drug were not identified as a market barrier. The fast-track process implemented in March 2009 will cut registration approval time for the majority of drugs, as most are previously registered in the United States or European Union.

The registration rules were well disseminated. The regulation on registration was one of the few laws reviewed for this report of which most parties interviewed had a copy, though not all the copies were up-to-date.

Drugs are admitted for registration in Albania only if they are manufactured in Albania or registered and marketed in at least one of the following markets: United States, European Union, Canada, Japan, Australia, and Switzerland (Law 9523). A second provision allows in drugs manufactured in Balkan countries with which Albania has trade agreements, if the drugs have been registered in the country of origin for at least two years. A “fast-track” process cuts the review process from 6-9 months to 30 days for drugs registered in the United States, European Union, Canada, or Australia (MOH 1588 as amended by MOH 73).

Policies requiring prior registration in developed markets may limit lowest-cost generic contraceptives, but may be appropriate for Albania’s small market. Affordability of contraceptives is a significant issue in Albania, where up to 80 percent of oral pill users are unable to afford the majority of nonsubsidized commercial brands (Tien and Rao, 2009). Many low-cost generic oral contraceptives are available from countries such as India and Brazil. If permitted to be registered for the Albania market, these generics could provide a more affordable range of price points on the market.

However, there is limited stakeholder support for loosening restrictions on drugs not previously registered in the “permitted” countries, due to cultural preference for European goods, quality concerns about drugs from Southern Hemisphere countries, and limited NCDC capacity to independently evaluate drug efficacy. A World Bank pharmaceuticals specialist noted that many generics manufacturers sell into the United States and Europe at fairly low prices, and would be eligible for import in Albania (Seiter, 2009). Although Albania may restrict the introduction of lower-cost generic contraceptives developed for emerging markets that are not marketed in the richest countries, the requirement on balance strikes a reasonable compromise.

**The role of the DNC should be clarified.** The DNC is an advisory body created in 1998 to provide technical and clinical input on drug registration decisions (MOH Order 525). Members are appointed by the MOH annually, with the intention that there be a breadth of clinical specialties represented. The DNC is also authorized to assist in the preparation of the list of reimbursable drugs under HII and the list of over-the-counter (OTC) drugs that may be sold without prescriptions, and to conduct clinical tests in compliance with World Health Organization (WHO)-approved practices.

Theoretically, the DNC is asked to conduct a second review of drug registration applications in order to provide expertise with regard to the pharmacological and clinical aspects of a drug, but in reality, this review is pro forma. Various sources described the DNC's role as bureaucratic, adding up to a month to the registration process with no real technical input.

The ministerial order authorizing the DNC has not been updated since 1998 and needs to reflect current market needs. Given that approved drugs must all have received prior approval from countries with rigorous testing and criteria, DNC oversight of the NCDC's review of application documentation appears unnecessary. Clinical advisors with expertise in particular therapeutic categories do have an appropriate role in determining which drugs should be included on the essential drug list, but the DNC rules order fail to provide any criteria for selecting members, or using clinical evidence to make decisions.

## 2.3 CUSTOMS AND IMPORTATION

**TABLE 2.3 CUSTOMS AND IMPORTATION LAWS AND DECISIONS**

<b>Key Laws &amp; Decisions (Date)</b>	<b>Description</b>
Law No. 8449 (May 1, 1999)	Customs Code of the Republic of Albania (not appended to this report)
COM Order 511 (July 30, 2004)	Requires control stamp including price to be affixed on registered drugs at point of import (not appended)
Law 9323 (Nov. 25, 2004)	Law on Drugs; of relevance, specifies drug trading provision, including permits as issued by NCDC and control stamps
Law 9461 (Dec. 21, 2005)	On the combined nomenclature of goods and the integrated customs tariff, changed and amended (not appended to this report)
COM Order 910 (June 18, 2008)	Establishes licensing authority of the MOH and Regional Public Health Departments to issues licenses for import/export of drugs and establishment of pharmacies
MOH Order 256 (July, 10, 2006)	On Import Permits for Unregistered Drugs, setting forth exceptions to registration based on emergency situations
Law 9981 (Sept. 08, 2008)	On the approval of the rates of customs tariff (not appended to this report)
Law No. 10008 (Oct. 27, 2008)	Changes and amendments to the Law on Drugs regarding licensing requirements of drug importers
MOH Order 591 (Oct. 30, 2008)	On Approval of Regulation on Licensing Procedures of Private Activities in Health Sector
MOH 682 (Dec. 12, 2008)	On Drug Import; reverts back to the procedures outlined for inspection and license issuance as outlined in Law No. 9323
COM 1672 (Dec. 24, 2008)	On approval and official publication of combined nomenclature of goods, 2009 (not appended to this report)
COM 144 (Feb. 11, 2009)	On Approving Self-Declaration Forms to Exercise Drug Wholesaling Activity, Marketing in Pharmacies and Pharmaceutical Agencies and Import and Export
Law No. 10081 (Feb. 23, 2009)	On Licensing, Authorizations, and Permits (not appended to this report)
<b>GAPS/RECOMMENDATIONS</b>	
<ul style="list-style-type: none"> <li>• Import process changes adopted in October 2008 did not have adequate stakeholder input, operational planning, or communication to affected parties. A more transparent and systematic process is needed to ensure coordination between MOH, NCDC, Customs, and IPH.</li> <li>• Prior to amending policies and procedures, extensive consultation is needed with all stakeholders</li> </ul>	

active in importation of pharmaceuticals.

- Importers and Customs officials clear guidelines on process changes with adequate advance planning time and effective communications on procedural requirements.
- Oversight by MOH of importation of medical devices (including condoms and IUDs) remains under development and may impose new requirements.

**Proposed changes:** Adoption of more systematic and transparent rulemaking process that invites input from affected parties, articulates the rationale for changes, provides long-term plan for implementation, and widely disseminates communications to stakeholder community.

## DISCUSSION

All modern contraceptive products in Albania are currently imported and therefore subject to the legal requirements for importation and customs clearance procedures as either drugs, medical devices, or non-food products.

### Import and customs procedures for drugs

The NCDC, responsible for drug registration and control (Law 9323), oversees the importation of contraceptives classified as drugs. NCDC exercises this function through the issuance of import permits. This import permit can be issued only for drugs that have undergone the registration process and that meet other licensing requirements.

As described by importers interviewed for this report, an importer of a registered drug applies for an NCDC Import Permit, which usually takes 1-2 days to receive. The importer then takes the permit with other documentation (invoice, certificates, pharmacology analysis, origin of manufacture) to the Customs Office. NCDC inspectors visit the customs house twice per week and know when consignments are passing through based upon the import permit. Once the shipments have passed inspection, a Permission of Use is issued, including the price of the drugs and control stamp, which is affixed to all the bottles and packets to be distributed. No customs duties or tariffs are applied to drugs, including oral contraceptives.

Exceptions to the registration rule exists for drugs with special authorization provided by the Minister of Health, and based on specific reasons such as in states of emergency, or drugs in the process of being registered (MOH Order 256). An import permit issued by the NCDC is still required for the importation of such drugs, and the same process of inspection and issuance of Permission of Use is applied.

Importers also are required to have a professional license to import, issued by the MOH. The applicant for this license must be a qualified pharmacist with a minimum level of work experience.

### Recent changes to import/customs procedures for drugs

Since 2006, the MOH has been working to expedite the customs clearance process for drug importers by reducing the bureaucratic requirements for drug importation and licensing. In October 2008, Parliament passed Law 10008, which aims to strengthen collaboration between the NCDC and Customs Office and eliminate the need for the import permit. Other streamlining measures included provision for drug distributors to receive an import license through a self-declaration process (see MOH Order 591 and COM Dec 144). Additionally, a

new framework law (No. 10081) was adopted in February 2009 to improve licensing and permitting for all applicable commercial activities.

In practice, the changes for drug import procedures had a number of weaknesses, which resulted in the breakdown of procedures and in Customs holding up drug consignments. The MOH responded with a stay on the amendments (MOH Order 682), a practical although not necessarily appropriate legal measure, which has reverted the practice and procedures for drug import and customs clearing back to the original.

Stakeholders interviewed cited several sources of confusion created by the new law: limited consultation with NCDC experts on the inspection procedures needed at Customs, inadequate planning and training to ensure that systems were in place to identify registered drugs, and poor communication between NCDC and Customs staff about the changes. Products were prevented from entering the country due to lack of paperwork that the October 2008 law had in fact eliminated. With the stay of the law, the NCDC is still issuing import permits, but because the language of the stay does not specify which articles are no longer in effect, the confusion continues. In addition, the newly authorized Regional Public Health Directors also have begun to issue import licenses.

Interviewees gave no examples of shipments of contraceptives being delayed by the regulatory transition, but clearly all pharmaceutical imports are threatened by poorly executed process changes going forward. Further clarifications and amendments to the drug import and custom clearance procedures and requirements are expected in the future, subject to the decisions of new policymakers following the recent election. Among the provisions under discussion is the creation of a new licensing authority. Advocacy groups concerned about a consistent supply of contraceptives should support broader systemic improvements to Albania's promulgation of new import procedures. These include clear communications about import requirements and adequate timeframes and resources to implement.

### Import and customs procedures for medical devices

Regulations governing the import of contraceptives classified as medical devices including condoms, IUDs, and pregnancy tests are less stringent than the licensing and permitting that apply to drugs. Products declared by the Goods Nomenclature as either medical devices or non-food items must still have certificates of analysis, certificates of origin, and invoices.

The MOH has drafted regulations to ensure minimum standards for the manufacture, marketing, clinical evaluation, and use of medical devices in Albania. This law has not yet been approved by the Council of Ministers, and its future is uncertain.

## 2.4 PRICING

**TABLE 2.4 PRICING LAWS AND DECISIONS**

Key Laws & Decisions (Date)	Description
COM Dec. 182 (April 25, 1995)	On Drug Marketing Prices
COM Dec. 511 (July 30, 2004)	On control stamp and price marketing procedures, describing required markings for approved drugs (not appended to this report)
Law 9323	Articles 50 and 51 provide the framework for the statement of drug prices and

(Nov. 25, 2004)	margins, and the role of the DPC
COM Dec. 56 (Jan 28, 2005)	On Calculation of Drug Production and Marketing Margin, providing for maximum mark-ups
COM Dec. 708 (Nov. 16, 2005)	Some additions to Drug Marketing Prices (COM Dec. 182), providing for retailers to affix control stamps for drugs already stocked
COM Dec 504 (Aug 8, 2007)	On Establishment and Function of the DPC
<b>GAPS/RECOMMENDATIONS</b>	
<ul style="list-style-type: none"> <li>• Price controls on drugs are based upon manufacturers' stated cost. Stronger assurance of claimed costs are needed to ensure prices are set fairly. <ul style="list-style-type: none"> <li>○ There is no systematic use of reference pricing for similar drugs sold in other countries in the region to ensure that prices are fair and competitive. The DPC may need technical assistance to build capacity to use reference pricing mechanisms.</li> <li>○ Inspections by both the NCDC and Customs officials should include cross-checking of price documentation to ensure the cost claimed is realistic and as stated.</li> </ul> </li> <li>• Through price regulations, margins are fixed for each player in the supply chain. A consolidated margin to be shared among importers, distributors, and retailers would increase flexibility in the event of exchange rate fluctuations, and would stimulate competition.</li> </ul> <p><b>Proposed changes:</b> COM Decision 504 should be amended to require use of reference pricing from other markets to verify manufacturers' stated costs, and ensure regular verification in all documents. COM Decision 56 should be amended to provide more flexibility in the establishment of margins shared among importers, distributors and retailers.</p>	

## DISCUSSION

Drug prices in Albania are established by the DPC, a permanent attachment of the MOH, chaired by the Directorate of Pharmaceuticals, with representatives from the MOF, HII, Ministry of Economy, Trade and Energy, and the Wholesalers Association.

To establish the price of a drug, marketing authorization holders of registered drugs declare their maximum price (in Lek) each year in a sealed envelope, based on their CIF. The CIF price, once approved, provides the basis on which marketing margins are calculated. Total permitted mark-ups are currently set at 51 percent. Of that maximum mark-up, importers get 12.5 percent, distributors 5.5 percent, and retailers 33 percent. Some reimbursed drugs are subject to different margins, upon special decision of the Council of Ministers.

The DPC approves a list of prices for all drugs, on a majority vote basis. The list then goes to the Council of Ministers for approval. The Pharmaceutical Department, which approves the final drug list, notifies the Customs Department, Tax Department, and other institutions of the approved prices.

Two regulatory changes could help put downward pressure on contraceptive prices. The first would require use of reference pricing to ensure stated prices are in line with international markets. The second would allow more flexibility on negotiation of marketing margins among the various distributors of pharmaceuticals.

Prices for hormonal contraceptives are prohibitive for large segments of the Albanian market (Tien and Rao, 2009). Albania is a small, under-developed contraceptive market, with poor economies of scale, so prices for imported drugs should be in line with other countries in the region. Instead, there are indications that drugs prices in Albania are higher than in similar markets (Witt, 2006; Gjenci, 2007).

There is no systematic use of mechanisms to ensure prices are not inflated for the Albanian market, in particular the use of price referencing for drugs and medical devices sold elsewhere (Forzley, 2007). These are easily found online, such as the International Drug Price Indicator Guide published by Management Sciences for Health. Use of reference pricing should be a required step in DPC approvals, to ensure that consumers are not overpaying.

Albanian Customs and the NCDC should also be encouraged to use their powers of inspection in a systematic way to cross-check the stated CIF price against other required documentation during the customs clearance process, including company contracts and bank transfer documents, to prevent document falsification. Ministerial orders should ensure that Customs and the NCDC have the capacities in place and clear mandates to collaborate and perform these duties.

Margins are set based upon declared CIF prices, and there is limited competition in the Albanian market, so there is incentive for all providers in the supply chain to keep the CIF high, and to extract the highest margin permitted. Several sources interviewed for this report stated that there would be more price competition if importers, distributors, and retailers were left to negotiate how to divide the permitted mark-ups, to facilitate price-lowering pressures from particular channels. Several importers also cited their inability to adjust prices midyear as a deterrent to price competition, particularly in the face of currency exchange fluctuations. For this reason, it is recommended that a single consolidated margin for contraceptives be adopted, to stimulate development of the contraceptive market.

## 2.5 REIMBURSEMENT

**TABLE 2.5 REIMBURSEMENT LAWS AND DECISIONS**

Key Laws & Decisions (Date)	Description
Law 7870 (Oct 13, 1994)	On Health Insurance in the Republic of Albania; outlines eligibility criteria, basic package of services, etc.
MOH Directive 716 (Dec 29, 2008)	Describes drafting of reimbursed drug list
MOH Rule No. 40 (Jan 29, 2009)	Criteria for removing or including drugs from reimbursement list
<b>GAPS/RECOMMENDATIONS</b>	
<ul style="list-style-type: none"> <li>• Contraceptives are not currently on the Drug Reimbursement List, and should be included. Reimbursement through national insurance schemes will promote broader use and is consistent with the RH Committee Strategy draft. A formal petition should be filed with the Drug Commission identifying how specific contraceptives meet the eligibility criteria.</li> <li>• Criteria for the inclusion or removal of drugs from the Reimbursement List should include price and economic criteria. Cost-effectiveness data for use of oral contraceptives will support government subsidies on the basis of long-term savings.</li> </ul> <p><b>Proposed changes:</b> Drug Reimbursement List should be expanded to include oral contraceptives.</p>	

## DISCUSSION

All prescriptions, from both public health centers and private clinics, are filled at private pharmacies. For drug costs incurred by HII beneficiaries, the HII reimburses the pharmacy in full or in part; if



reimbursement is not for the full cost, the patient pays the remainder out of pocket. HII beneficiaries include paid members and other eligible parties such as veterans, pensioners, and people with disabilities. Approximately 45 percent of Albanians are covered by insurance (Gjeci, 2007).

The HII reimburses the cost of the drugs, but the decision of which drugs are on the list is done by the Commission of Designing and Reviewing of the Reimbursable Drugs List, also called the Drug Commission. The Minister of Health chairs the commission; other members include the head of HII, and representatives from the IPH, the NCDC, and directors of national hospital services. There are no clinical criteria for the selection of members. Commission members review the list of reimbursed drugs on an annual basis against a number of newly developed eligibility criteria.

No contraceptives have ever been on the Drug Reimbursement List. According to one manufacturer interviewed, they have been trying – unsuccessfully – to get an IUD on the reimbursement list for two years, arguing for both its medical benefits as well as contraceptive properties. Global surveys of FP best practices document that health insurance coverage of FP products is effective in improving FP services and outcomes (Berdzuli et al., 2008). Adding contraceptives to Albania’s list of reimbursable drugs would give manufacturers more incentive to enter the market with new products, and increase usage (Tien & Rao, 2009).

Advocacy to include contraceptives on the Drug Reimbursement List should be a high priority for stakeholder efforts to improve contraceptive supply in Albania. Advocacy should include a presentation of a formal case to the Drug Commission, with extensive lobbying of member organizations, demonstrating the costs and benefits of preventing unwanted and unplanned pregnancies. The newly adopted regulations establishing criteria for inclusion include priority for primary health care drugs.

## 2.6 TAXES AND TARIFFS

**TABLE 2.6 TAXES AND TARIFFS LAWS AND DECISIONS**

Key Laws & Decisions (Date)	Description
Law No. 7928 (April 27, 1995)	On Value Added Tax (not appended), which provides for 20% tax on non-exempt items
Albanian Constitution (October 21, 1998)	Albanian Constitution, specifically Article 155, regulates taxes, facilitation, and exemptions from taxes (not appended)
MOH Protocol 1766 (May 5, 2008)	Ruling from Directorate of Legal and Licensing Services to NESMARK
Law No. 10003 (October 6, 2008)	On Changes and Amendments to Law 7928 on Value Added Tax
<p style="text-align: center;"><b>GAPS/RECOMMENDATIONS</b></p> <ul style="list-style-type: none"> <li>• Contraceptive products subject to 20% VAT include medical devices including condoms, IUDs, and pregnancy tests, resulting in higher end user prices. All contraceptive products should be exempt from the VAT to improve affordability and access. Broad language should be used to ensure exemption from VAT for all levels of the supply chain.</li> </ul> <p><b>Proposed changes:</b> Section 25/2 of Law 7828 should be amended to add the following: “Contraceptives of any kind are exempted supplies.”</p>	

## DISCUSSION

Albania’s VAT, adopted in 1995, is currently applicable to all contraceptive products at a rate of 20 percent. There is an exemption for the “supply of medicines,” presumably adopted to promote the broadest possible access to clinically required pharmaceuticals. Contraceptive drugs such as oral contraceptives, emergency contraceptives, and injectables are classified as exempt medicines. There is no exemption for medical devices of any kind, and the MOH has made clear that condoms, IUDs, and pregnancy tests are not exempt (Letter to NESMARK from MOH). Even the condoms and IUDs purchased with public funds through the UNFPA on behalf of the MOH’s own RH programs are subject to VAT, essentially taxing the budget of one agency to fund others.

Currently a tariff of 2 percent is applied to medical devices, depending on the certificate of origin – products from European Union (EU) countries, Central Eastern Free Trade Agreement (CEFTA) countries, and all other countries holding free trade agreements with Albania are exempt. Customs duties are applied to the value of the good at CIF price and the VAT (in this case, 20 percent) is applied to the value of price and customs duties, thus equating to 22.4 percent.

The application of the 20 percent VAT on contraceptive products such as condoms is inconsistent with Albania’s goals of promoting availability of contraceptives as expressed in its 2003 National Contraceptive Security Strategy. The VAT is passed directly on to consumers, resulting in higher prices, and reducing the number of users accessing condoms in the private sector. Price is a particularly significant factor for some of the most vulnerable sexual health risk groups, and any price reduction could therefore have a major impact on condom purchase and use.

Stakeholders active in the RH area in Albania generally shared the view that the VAT has a dampening effect on the sale of condoms and contraceptive products. In the most recent analysis of sustainable financing for contraceptives in Albania, a Contraceptive Security Report confirmed that the lowest-income group in Albania cannot afford most of the condoms on the market, with the exception of the subsidized socially marketed brands (Tien and Rao, 2009). The VAT on condoms has also impacted the supply side, with several wholesalers reporting that the tax generates resistance from pharmacists who want to avoid the paperwork entailed.

Under the Albanian Constitution Art. 155, taxes can only be changed through approval of Parliament. A broad advocacy campaign with support from donors, NGOs, the Order of Pharmacists, health care institutions and providers, and commercial suppliers should be undertaken to make the political, technical, and policy case including cost/benefit analyses for eliminating the VAT on non-drug contraceptives.

## 2.7 PRESCRIBING

**TABLE 2.7 PRESCRIBING LAWS AND DECISIONS**

Key Laws & Decisions (Date)	Description
MOH Order 475 (Oct. 7, 2004)	Doctors must prescribe drugs except for those drugs on the MOH list of drugs that may be sold without prescription. (Based on predecessor Law on Drugs 7815)
Law 9323, Art. 41	Single provision instructs the MOH to establish rules of prescribing for persons

(Nov. 25, 2004)	with medical qualifications
<b>GAPS/RECOMMENDATIONS</b>	
<ul style="list-style-type: none"> <li>• Law requiring clients to have doctor prescriptions to purchase drugs has not been implemented; there are no rules to guide prescribing practices for doctors, nor enforcement of the prescription requirement at pharmacies. Mandatory prescription policies for contraceptives would inhibit access absent widespread compliance with approved clinical protocols.</li> </ul> <p><b>Proposed changes:</b> No changes should be implemented at this time to enforce prescription requirements for contraceptives. Advocacy efforts should support systemic improvements underway for physician pre-service and in-service training in evidence-based medicine.</p>	

## DISCUSSION

Albanian law requires customers to have prescriptions in order to purchase any drugs sold in retail pharmacies, unless the drug appears on the official nonprescription drug list. There are no contraceptives on the nonprescription drug list, so by law, a doctor’s prescription is required to buy hormonal pills and emergency contraceptives. However, stakeholders across the spectrum confirmed that this law is not enforced and many patients bypass doctors and purchase drugs directly from pharmacists, without prescriptions. From the perspective of expanding access, this is positive: OTC sales makes FP hormonal methods more easily available for those who choose to limit fertility.

In several respects, enforcement of the prescription requirement for contraceptive drugs would be counterproductive to RH goals of broader access to FP products. Doctors might impede access, based on their lack of information or negative attitude toward modern contraceptives resulting in refusals to issue prescriptions or requiring frequent re-subscriptions (ASTRA Network, 2007). Other barriers include the time and financial costs of visits to private health clinics, where many women go for primary health care needs (JSI, 2007). Prescribing practices among doctors are described as weak, suffering from poor compliance with recognized good practices and standards, such as the WHO criteria of appropriateness, safety, effectiveness, and value for money. “Informal payments” linked to prescriptions are widespread, and there are reports of doctors and pharmacists colluding to process ghost prescriptions (Gjeci, 2007).

In light of these barriers to obtaining contraceptive prescriptions, and lack of prescription requirement enforcement by the MOH, there is little incentive for patients to follow the official channels. One exception would be if the drugs were reimbursed through national insurance schemes, in which case there is more regular enforcement (and patient benefit) from securing prescriptions for acquiring needed products.

A number of efforts are underway in Albania to strengthen overall provider practices, including prescribing practices. This includes projects by USAID, UNFPA, Red Cross, and others, as well as planned development of evidence-based treatment guidelines and in-service training by the National Center of Quality, Safety and Accreditation of Health Institutions (NCQSAHI) and HII’s development of guidelines on prescribing practices. Improved knowledge and practice of health personnel are necessary conditions precedent to imposing strict enforcement of prescription-based access to contraceptives. Other programs, such as USAID’s C-Change project, are working to improve pharmacist knowledge and awareness of modern contraceptive options so that they support public information and education campaigns. RH advocates should support these systemic changes to improve quality of FP services and oppose enforcement of prescription requirements at this time.

## 2.8 PROMOTION

**TABLE 2.8 PROMOTION LAWS AND REGULATIONS**

Key Laws & Decisions (Date)	Description
Law 9323, Art. 52 (Nov 25, 2004)	<ul style="list-style-type: none"> <li>▪ Prohibits consumer advertising other than for promotion of OTC drugs; limits promotion of prescription drugs to literature or professional activities targeting the scientific and clinical community</li> <li>▪ Rules on promotion to be approved by the Minister of Health</li> </ul>
<p style="text-align: center;"><b>GAPS/RECOMMENDATIONS</b></p> <ul style="list-style-type: none"> <li>▪ Regulations have not been implemented governing drug advertising. To protect both consumers and suppliers, a Code of Ethics should be adopted by industry to guide promotional activities.</li> </ul> <p><b>Proposed changes:</b> Industry associations, the Order of Pharmacists and the MOH should endorse a Code of Ethics for Drug Promotion, based upon the Code of the European Federation of Pharmaceutical Industries and Associates, adapted to fit the Albanian market.</p>	

## DISCUSSION

The 2004 Law on Drugs clearly prohibits drug advertising to consumers, other than for OTC drugs. Like the law on prescriptions, this law has not been addressed, and the MOH has not promulgated implementing regulations.

The lack of guidelines on drug advertising creates uncertainty for marketers and may create risks for consumers, particularly as the market becomes more competitive. Stakeholders interviewed for this analysis gave conflicting reports and demonstrated a wide range of interpretation of rules on promotion. Some sources were unaware of any provision against advertising to consumers, and others stated that the law applies only to unregistered drugs. Some reported seeing consumer ads for branded pharmaceuticals, and others said that the only drugs advertised in mass media are on the approved OTC list. The Order of Pharmacists provided a copy of this OTC list, but acknowledged that it was out of date.

Policies are needed to establish guidelines to provide broad consumer access to accurate information and inform marketing companies on permitted activities. Global best practices for pharmaceutical marketing are widely available, such as the European Federation of Pharmaceutical Industries and Associates (EFPIA) standard code of ethics. This code should be adapted for the Albanian market and endorsed by a cross-section of stakeholders including the Order of Pharmacists, industry associations, MOH, and other relevant agencies to support widespread dissemination and institutionalization. This code could then form the basis for future rules and regulations on drug promotion required by the Law on Drugs.

# 3. ADVOCACY STRATEGY

## 3.1 BACKGROUND/CONTEXT

Section 2 provided an overview of legal and regulatory gaps and recommendations to expand the contraceptive market in Albania. This section addresses how those recommendations might be implemented, through advocacy efforts aimed at improving RH policy and practices. One of the basic rights established in Albania's Reproductive Health Law (No. 8875) is the right of all individuals and couples to benefit from the use of secure and affordable methods of FP, according to their choice. The barriers outlined in Section 2 interfere with the use of affordable methods, and are therefore relevant to an overall strategy to improve RH in Albania.

Many of the stakeholders interviewed for this report have been active in MOH-led RH Council meetings and activities of its predecessor National RH Commission. While applauding the progress that has been made to improve contraceptive prevalence, they shared common concerns. The record of the past decade indicates that valuable policy strategies have not been implemented because budget resources were never allocated. The MOH RH Unit is understaffed and underfunded. Political commitment to RH waivers with the press of other public demand, and there is no champion willing and able to keep contraceptive security on the national health agenda (Albania Family Planning Project, 2006). Broader health sector reforms underway, such as decentralization and financial restructuring, can be threats to existing programs; watchdogs are needed to ensure that RH needs are not orphaned. Albania lacks a culture of citizen advocacy, with no history of organized effort to champion FP needs.

Within this context, a number of sources interviewed pointed to the ACPD as the natural leader for the cause. Based upon several discussions with ACPD's executive director, it would appear that the ACPD is ideally positioned to become the catalyst for the policy changes needed to fulfill the Albania government's RH commitments.

The ACPD is a volunteer-run nonprofit organization, established in 1993, that works for the improvement of the health and well-being of all Albanians by advocating appropriate legislation and policies, raising awareness about health life styles and human rights, and promoting equal access to quality information and affordable services and supplies. The ACPD experience includes advocacy for adoption of the gender equality law and law against domestic violence, working at both the national and local levels. It is a member of the International Planned Parenthood Federation (IPPF).

The ACPD has just launched a major five-year program to nurture a civil society alliance to promote RH policies in Albania. Supported by DFID's Citizens Voice & Accountability Project, the IPPF has chosen three countries in the Europe and Eurasia region in which to implement interventions aimed at strengthening civil society advocacy for sexual and reproductive health rights. Albania is one of the three countries, and the ACPD is the IPPF affiliate spearheading this effort.

## 3.2 ACPD ADVOCACY PLAN TO PROMOTE RH IN ALBANIA

The ACPD shared its approach, accomplishments to date, work plan, areas of focus, and tentative objectives, which are still in development. These objectives are 1) to secure funding to implement by 2012 the national RH Council strategy currently being finalized, 2) to ensure national and local government accountability for implementation of programs related to maternal and child health (MCH),

FP, and adolescent health, and 3) to strengthen the capacity of Albanian CSOs to influence the policy- and decision-making processes on sexual health and reproductive rights issues. These objectives track with the purpose of this regulatory analysis, and provide a good context through which to promote policy changes to strengthen private sector provision of RH/FP.

The ACPD intends that the advocacy alliance be as inclusive as possible. Contacts have been initiated with local CSOs in the fields of healthcare, women’s rights, children’s rights, and human rights. Other stakeholders invited to participate in a spring 2009 planning workshop in Brussels included representatives from Albania’s hospitals, local governments, media organizations, MOH, IPH, UNFPA, and RH/FP program officers of USAID projects. Activities planned for the future include advocacy training workshops, preparation of fact sheets and lobbying materials, media training, surveys and research, conferences, local government roundtables, and coordination with EU Parliamentarians and other influential persons. Trainings, advocacy, and media outreach will take place throughout the country.

The ACPD is targeting three components of the National RH Committee’s strategy in their advocacy campaign: MCH, FP, and adolescents. ACPD intends to review, disseminate, and utilize the recommendations summarized in Section 2 of this report as inputs to developing specific policy targets related to strengthening the availability and accessibility of modern contraceptives. The report serves as a resource to help prioritize lobbying efforts, develop arguments to support needed changes, and provide a shared starting point regarding policy barriers to private sector contraceptive supply.

### 3.3 IMPROVING RH IN THE CONTEXT OF MCH POLICIES

ACPD’s strategy is to build support for more sensitive FP provisions through policy objectives that address broader MCH factors. Toward this end, the ACPD requested assistance in developing a framework for national MCH policies through which RH policy changes could be interwoven. PSP-One has experience in conducting broad legal and regulatory assessments related to strengthening RH/FP programs (Ravenholt et al., 2005). Provisions related to MCH policies are complementary to RH/FP services because MCH and RH/FP frameworks share similar elements: in both cases, provisions are needed for clear stewardship at the national level, with enforced standards of care.

Below is a chart outlining the key elements of a MCH framework to guide future policy strategy, based upon the 10 Essential Policies of the Public MCH Program Functions Framework (Grason and Guyer, 1995). MCH policies related to safe motherhood, antenatal, and neonatal care should be addressed through mandates related to service delivery access, promotion of evidence-based clinical guidelines adopted by professional associations, and provider training, accreditation, and oversight. These policy areas apply equally to other FP/RH services.

**TABLE 3.3 MCH POLICY FRAMEWORK**

Policy Concerns	Areas for ACPD Focus
<p><b>Inclusion of maternal and newborn care in primary health care</b></p>	<p>Access to basic MCH services through primary health care centers should include the following services: pregnancy testing, antenatal visits, delivery care, postnatal care, RH/FP counseling, immunization, breastfeeding initiation and support, and prevention and diagnosis of sexually transmitted diseases (WHO 2007).</p> <p>Albania and WHO/Europe 2008-2009 biennial agreement on improving maternal, child, and adolescent health services includes commitment to improve quality care in primary health care to maximize access to</p>

	<p>vaccines, integrate other essential child health interventions with immunization, and improve access, quality, and use of MCH care (WHO, 2008).</p> <p>Monitoring is needed to ensure government commitments are abided by and reported on a regular basis, with funding provided for scale-up and training.</p>
<b>Data collection and analysis</b>	<p>Accurate information on MCH outcomes and delivery of services is needed in order to monitor indicators, allocate state resources, and determine whether services are meeting needs of the population.</p> <p>MCH outcomes to be analyzed at the national level include fertility rates, pregnancy outcomes, cause-specific maternal and neonatal mortality and morbidity, and utilization of services.</p> <p>Indicators and targets are needed to measure effectiveness of MCH policies such as:</p> <ul style="list-style-type: none"> <li>• percentage of women who make antenatal visits</li> <li>• percentage of women who breastfeed exclusively for first 6 months</li> <li>• percentage of infants brought in for immunizations within 6 weeks of birth</li> <li>• percentage of women who say they have received information on FP from health care provider</li> </ul>
<b>Financing of MCH services</b>	<p>Advocacy is needed to ensure adequate budgetary resources are allocated both for those MCH services made universally available and those service covered through insurance. Albania health financing law, in development, will determine a mechanism for funding critical MCH services including pregnancy care, safe delivery, and newborn care.</p> <p>To reduce barriers to access, policy should require providers of MCH services to be transparent in the charging for services. Lists of services available free of charge, those requiring co-payments, and those covered by insurance or by patients should be posted and printed in brochures.</p>
<b>Adoption and enforcement of evidence-based clinical guidelines</b>	<p>Provider standards of care approved by clinically qualified professional organizations are needed to ensure safe and effective treatment and prevention services.</p> <p>Albania lacks standard protocols of treatment, or evaluation indicators for high quality primary care (Witt, 2006; Hana, 2008). Various USAID-funded projects such as Partners for Health Reform <i>plus</i> (PHR<i>plus</i>), PRO Shëndetit, and ACCESS have supported development of evidence-based clinical guidelines used in pilot settings, but these have never been endorsed at the national level.</p> <p>The National Center of Quality, Safety, and Accreditation of Health Institutions (NCQSAHI) is the lead agency responsible but does not appear to have necessary government budget or authority to push standards through.</p> <p>Albania has been participating in the South Eastern Europe Health Network, a collaborative regional efforts to improve delivery of MCH services (<a href="http://www.imnhsee.com/ReportOf1stMeetingOfIMNH_Project.pdf">http://www.imnhsee.com/ReportOf1stMeetingOfIMNH_Project.pdf</a> and <a href="http://www.euro.who.int/document/SEE/IMNH_Split_rep.pdf">http://www.euro.who.int/document/SEE/IMNH_Split_rep.pdf</a>). Workshops on Clinical Guidelines Development were held to build national capacity</p>

	<p>for implementation of guidelines and protocols in the fields of maternal and neonatal health care. (South Eastern Europe Health Network, 2006; South Eastern Europe Health Network, 2007).</p> <p>Sample guidelines are available from a variety of government and academic sources such as the UK's Royal College of Obstetricians and Gynecologists (<a href="http://www.rcog.org.uk/womens-health/clinical-guidance">http://www.rcog.org.uk/womens-health/clinical-guidance</a>). NCQSAHI and Albania's professional associations bear responsibility for adapting these clinical guidelines to local contexts, and should support implementation technically and financially including routine monitoring.</p> <p>Lack of evidence-based MCH guidelines is a key gap in quality care, and should be addressed through a MOH-led process. A civil society campaign could be instrumental in monitoring adoption, promulgation, and enforcement.</p>
<p><b>Training and institutionalization</b></p>	<p>Pre-service training programs and in-service training for continuing medical education should include evidence-based guidelines.</p> <p>Approved clinical guidelines and protocols should be incorporated into approved curricula of medical education and continuing medical training for licensing. A mechanism is needed to ensure new protocols are updated regularly in required training and certification programs. A supportive supervision system should also be put in place.</p> <p>Accredited courses and training programs should include evidence-based research on FP methods, antenatal and postnatal care, labor management, abortion, and post-abortion care.</p>



## 4. CONCLUSION

This report provides an inventory of current laws and regulations relevant to private sector supply of contraceptives. Key recommendations for stimulating the supply side of Albania's contraceptive market through regulatory changes include clarifying the legal status of SMOs, eliminating the VAT on all contraceptive products, and including contraceptives on the Drug Reimbursement List under the national health insurance. This analysis is intended to guide donors about regulatory gaps and possible solutions to address them.

These recommended changes should be woven into the broader RH reforms already underway in Albania. Low demand is the biggest barrier to more expansive supply, and commercial contraceptive suppliers indicate that higher demand will translate into new products and broader supply. Consistent with this need, USAID and other donors are funding consumer education and demand-generation efforts for modern contraceptives, as well as other health sector strategies to improve provider knowledge and training critical to increasing contraceptive use. This report suggests ways to complement demand-generation efforts in future market strengthening programs.

In addition to mapping the regulatory landscape for contraceptive supply, USAID's objectives included supporting local CSOs as necessary partners and FP/RH change agents. The ACPD is well positioned to serve as local champion, through its five-year strategy to increase government accountability for improving RH through programs involving all aspects of FP and MCH. The focus of this report, on improving contraceptive supply, is intended to serve as a resource for the ACPD and its CSO alliance as they prioritize policy changes needed to ensure that the government delivers on its RH commitments.

The need for the regulatory mapping exercise undertaken for this report reflects a significant limitation in Albania's current process for keeping people informed about current rules governing the country. There was no centralized place in which relevant ministerial decisions could be located, requiring significant time and expense to catalogue existing law. This weakness in Albania's rule of law is one that will affect USAID and all public health stakeholders. Although general administrative practices regarding how laws and ministerial decisions are disseminated is tangential to RH, advocacy is needed to strengthen the process as well as the outcome of government decision-making. To improve government accountability and compliance, advocates for improved FP/RH services and products should take every opportunity to promote not only improved policies and the budget allocations to fund them, but also the immediate posting of all ministerial decisions online in an accessible format.



# ANNEX A: LIST OF SOURCES INTERVIEWED

## Ministry of Health

**Deputy Minister:** Zamira Sinoimeri

**Dept of Pharmacy:** Director Anjeza Rustemi  
Linda Ternova

**Medical Device Management Unit:** Office Head Arjon Bregu  
Ledina Picari

## National Center for Drug Control

**Director** Besnik Jakaj

**Juridicial Dept.** Migena Rizaj; Edlira Naqallari

## Drug Nomenclature Commission

Dr. Leonardo Nardi, University of Tirana, Dept of Pharmacology

## Health Insurance Institute

**General Director:** Elvana Hana

**Phamaceutical Dept:** Besnik Bruci

**Legal Dept:** Fjoralba Memia

## Donors/Multinational and Bilateral

**World Bank:** Lorena Kostallari, Senior Operations Officer

**WHO:** Dr. Anshu Basberjee, Representative Albania:  
Dr. Vasil Miho, Liaison Officer/Dep Head of Office

**UNFPA:** Flora Ismali, Director  
Elsona Agolli, Family Planning

**Italian Cooperative:** Francesca Fondi, Technical Assistant Health and Education

## **USAID Health Sector Projects**

**JPEIGO ACCESS:** Galina Stolarsky, Country Program Manager

**AED C-CHANGE:** Berengere de Negri, COP  
Arian Boci, Technical Officer

**URC PRO Shendiit:** Paul Richardson, COP

## **Manufacturers**

**Bayer Schering Pharma:** Ilir Teneqexhi, Country Div. Head  
Orjana Janushaj, Product Man.

**Activas:** Fatos Rexha, Director  
Erisa Arapi –Regul & Logistics

## **Importers & Wholesalers**

**Marketing & Distribution:** Artur Marika, sales manager

**OES Distrimed:** Ermal Rizaj, Administrator  
Orjada Jaho, Administrator

**ViniPharma Medical Group:** Hervin Fora, General Director

**Rosman:** Mr. Dritan Kukuqani (previously Customs Official in Rinas)

## **Pharmacists**

**Order of Pharmacists:** Ariani Jaupllari, Head of Order

## **Social Marketing**

**Nesmark:** Aridan Paravani, Executive Director

## **NGOs:**

**ACPD:** Elona Egjebrea Hoxha, Director  
Dr. Erjeta Dobi, Project Coordinator

## **Local Legal Experts**

Zyhrada Kongoli, Customs

Fatmir Kazazi, Tax

Andi Nano, Health Finance

# ANNEX B: LIST OF APPLICABLE LAWS AND REGULATIONS

Albanian Master List Laws and Policy Affecting Contraceptive Supply

(Categorized by source, date order)

DOCUMENT	Date Description	Page # Annex C
<b>Laws enacted by Parliament</b>		
Law 8875	April 4, 2002 <b>Law on Reproductive Health</b>	35
Law 9150	Oct. 30, 2003 <b>Law On the Order of Pharmacists</b>	36
Law 9323	Nov. 25, 2004 <b>Law on Drugs and Pharmaceutical Service</b>	42
Law 9523	April 25, 2006 <b>Amendment to 9323 re: permitted countries where previously registered, penalties</b>	59
Law 9644	Nov. 20 2006 <b>Amendment to 9323 re: provisions on drug pricing, drug pricing commission</b>	62
Law 10008	October 27, 2008 <b>Amendment to 9323 re: revisions to import license, inspection authority, regulation of pharmacies</b>	64
<b>Council of Ministers Decisions</b>		
COM 182	April 25, 1995 <b>On Drug Marketing Prices</b>	69
COM 56	Jan. 28, 2005 <b>On Calculation of Drug Production and Marketing Margin</b>	71
COM 708	Nov. 16, 2005 <b>Amending Dec. 182 re: drug marketing prices</b>	72
COM 504	Aug. 8, 2007 <b>On Establishment and Functioning of Drug Pricing Commission</b>	73
COM 910	June 18, 2008 <b>Licensing of private sector</b>	75
COM 144	Feb. 11, 2009 <b>On Approving Self-Declaration Forms to Exercise Drug Wholesaling Activity, Marketing, Import, Export</b>	77

<b>DOCUMENT</b>	<b>Date Description</b>	<b>Page # Annex C</b>
<b>Ministry of Health Decisions</b>		
MOH NESMARK Agreement	1997 <b>NESMARK Project and Financing Agreement between KfW, NESMARK, MOH, MOF</b>	80
MOH 525	1998 <b>On Functioning of Drug Nomenclature Commission</b>	85
MOH 475	Oct. 7, 2004 <b>On Medical Prescriptions</b>	87
MOH 256	Oct. 7, 2006 <b>On Import Permits for Unregistered Drugs</b>	89
MOH 1766	May 5, 2008 <b>Letter Ruling to Nesmark on applicability VAT to devices and drugs</b>	90
MOH 591	Oct. 30, 2008 <b>Changes procedures for licensing, customs</b>	91
MOH 682	Dec. 12, 2008 <b>On Drug Import abeying MOH Order 591</b>	96
MOH 40	Jan. 26, 2009 <b>Criteria for Removing or Including Drugs from Reimbursement List</b>	97
MOH 73	March 3, 2009 <b>Amends registration regulation to add fast-track procedures</b>	99
<b>Other Relevant Laws and Decisions (Not Translated or Appended)</b>		
Law 7870	Oct. 13, 1994 <b>On Health Insurance</b> (eligibility criteria, basic package of services)	
Law 7928	April 27, 1995 <b>VAT Law</b>	
Albanian Constitution, Art. 155 (21.10.1998)	Oct. 21, 1998 <b>Provides for taxes and exemptions</b>	
Law 8449	Jan. 27, 1999 <b>Customs Code of Albania</b>	
COM 205	April 13, 1999 <b>Implementing provision of the Customs Code</b>	
Law 8788	May 7, 2001 <b>On Not-for-Profit Organizations</b>	
COM 511	July. 30, 2004 <b>Additions to Dec. 182 on Drug Marketing Prices</b>	
MOH 1588	May 25, 2005 <b>MOH regulations on drug registration</b>	
Law 9461	Dec. 21, 2005 <b>Amending Customs Code</b>	
Law 9981	Sept. 8, 2008 <b>On the approval of the rates of customs tariff</b>	
Law 10003	Oct. 6, 2008 <b>Amending VAT</b>	
COM 1672	Dec. 24, 2008 <b>On approval, official pub of combined nomenclature of goods</b>	

<b>DOCUMENT</b>	<b>Date Description</b>	<b>Page # Annex C</b>
MOH 716	Dec. 26, 2008 <b>On Drafting and Revision Commission of Reimbursed Drug List</b>	
Law 10081	Feb. 23, 2009 <b>Law on Licensing, Authorizations and Permits</b>	





# ANNEX C: COPIES OF TRANSLATED LAWS, REGULATIONS, AND DECISIONS

## Law 8875 REPUBLIC OF ALBANIA THE ASSEMBLY - LAW

### "ON REPRODUCTIVE HEALTH" dated 04.04.2002

In reliance with the article 78 and 83 point 1 of the Constitution, on the proposal of the Council of Ministers

THE ASSEMBLY OF THE REPUBLIC OF ALBANIA

DECIDED CHAPTER I

General Provisions  
(or Definitions)

#### ARTICLE 1

This law regulates the organisation, functioning and supervision of all activities that are carried on in the field of reproductive health, in private and public health institutions, protects the reproductive health rights of the individual and couple, and ensures that reproductive rights of every individual are protected in compliance with the national laws and policies and other well-known international principles.

#### ARTICLE 2

Reproductive health (RH) is general physical, mental and social well-being related to the system of reproduction and its functions and processes and not only the lack of the diseases and disabilities but it implies that people should have a satisfied and secure sexual life.

It means the ability of people to reproduce and their freedom to decide on the manner and time of reproduction, to be informed where and how to find such services.

#### ARTICLE 3

Care for reproductive health means an entirety of methods, techniques and health services that affect reproductive health of people, preventing and solving their problems.

Care for reproductive health includes:

- a) services and counseling, information, education and communication for family planning
- b) services and education for before during and after birth especially breastfeeding

## **Law 9150**

**No.9150, dated 30.10.2003**

### **ON ORDER OF PHARMACISTS IN THE REPUBLIC OF ALBANIA**

Pursuant to the Articles 78 and 83, item 1, of the Constitution, upon the proposal of Council of the Ministers,

THE ASSEMBLY OF THE REPUBLIC OF ALBANIA

D E C I D E D:

CHAPTER I

GENERAL PROVISIONS

Article 1

1. For the purpose of preserving high quality of service as well as of the application of the rules of morale and pharmaceutical professional ethics, the Order of Pharmacists shall be established.
2. The Order of Pharmacists is a public entity, which is composed of individuals who practice the profession of the pharmacist in the Republic of Albania and represents their professional interests at the level of institutional partnership.

Article 2

1. The mission of the Order of Pharmacists is to preserve and guarantee the high level of the professional and scientific education and training of the pharmacists, the exercise of profession, in accordance with the scientific requirements, norms of medical ethics of the Albanian Code of Pharmaceutical Deontology and of the protection of patients and customers from the violation of mandatory norms.
2. For the accomplishment of such mission, the Order of Pharmacists shall:
  - a) register pharmacists in a separate book;
  - b) oversee the exercise of professional duties in accordance with the requirement of pharmaceutical sciences and pharmaceutical legislation;
  - c) cooperate with educational and scientific institutions on the compilation and planning of the curricula of scientific qualification, of postgraduate programme and continuous training of pharmacists;
  - ç) monitors the application of the requests of the Albanian Code of Pharmaceutical Deontology, in function of protecting the interests of patients and consumers;
  - d) grant and withdraw the individual right to practice this profession.

Article 3

1. The Order of Pharmacists shall oversee that rights and duties of the individuals who exercise the profession of pharmacists in the Republic of Albania are observed in compliance with the rules of the Albanian Code of Pharmaceutical Deontology, in order to protect the population from the abuse with the profession and violations of pharmaceutical ethics, as well as from other activities that prevent the due pharmaceutical care.

2. The Order of Pharmacists shall protect pharmacists from any arbitrary action by the public or private administration in the course of exercising the profession.

#### Article 4

1. Members of the Order of Pharmacists shall be those individuals of Albanian citizenship who have graduated as pharmacists in or out the Republic of Albania, accept the Albanian Code of Pharmaceutical Deontology and exercise such activity in the sectors of pharmaceutical production, service and distribution, in-patient and out-patient sector, public and private sector or in other health sectors.

2. Excluded from such obligation, but not from the right to become members of the Order of Pharmacists, are those pharmacists who are employed in the public administration, as long as they do not exercise a real pharmaceutical activity.

#### Article 5

The foreign citizens who want to exercise the profession of the pharmacist in the pharmaceutical sector of the Republic of Albania should become members of the Orders of Pharmacists, should know and implement the Albanian Code of Pharmaceutical Deontology, as well as all the legal and sub-legal acts that govern the pharmaceutical and health service in the Republic of Albania.

#### Article 6

1. No individual can exercise the profession of the pharmacist in the Republic of Albania without being member of the order of Pharmacists.

2. Employers of the state or public enterprises and private subjects are not allowed to recruit them in contradiction with this provision.

3. The National Council of the Order of Pharmacists shall define the adherence criteria of pharmacists to this order.

#### Article 7

The Order of Pharmacists, in the course of exercising the proper duties, is in contact, according to the affiliation, with the Ministry of Health, with other institutions, as well as with other public or non-public bodies at the local and central level. The Order of Pharmacists shall take part in the designation of draft laws and of important documents of Albanian pharmaceuticals.

#### Article 8

1. The Order of Pharmacists shall avail of its own budget, which shall administrate in compliance with the applicable financial rules.

2. The financial resources of the Order of Pharmacist include:

- a) membership quota;
- b) fees of registration and granting of individual practice right;
- c) various local and foreign donations and other legitimate incomes.

3. The Order of Pharmacists shall use the incomes generated in the course of exercising its activity to accomplish the mission attributed to it by this law.

## CHAPTER II

### ORGANIZATION AND MANAGEMENT

#### Article 9

The main bodies of the Order of Pharmacists include:

- a) assemblies;
- b) councils;
- c) disciplinary commissions;
- ç) Committee of Registration and Granting Right to Professional Exercise.

#### Article 10

1. The General Assembly is composed of members of regional councils.
2. The General Assembly shall elect the National Council. The elections for the National Council shall be conducted every four years, with the right to re-election. The regional assembly is composed by all the member representatives of the regional Order of Pharmacists. The regional Assembly shall elect the regional council. The elections for the Regional Council are held every 4 years, with the right to re-elections.

#### Article 11

1. The National Council shall have the mandatory presence of the President of the Order of Pharmacists, his/her deputy, the presidents of the regional councils, as well as one representative from the Ministry of Health, Health Insurance Institute and the Faculty of Medicine.
2. The General Assembly shall elect the president and his/her deputy on a four year term, with the right of re-election. The position of the president is irreconcilable with other leading functions in the public administration.
3. The National Council appoints and removes the Secretary General.
4. The National Council makes decisions with the majority of voters, when more than half of its members are present.

#### Article 12

The National Council of the Order of Pharmacists shall draft and approve the Code of Pharmaceutical Deontology, as well as the statute of the Order of Pharmacists.

#### Article 13

The National Council, in compliance with the mission of the Order of Pharmacists, provided for by the provisions of this law, shall have the following responsibilities:

- a) appoints and approves the organizational structures of the regional councils and of the National Council
- b) establishes the membership quota and registration fee;
- c) manages movable and immovable properties of the Order of Pharmacists at the national level, by allocating the funds to be administered by the regional councils;
- ç) oversee all the activities and administration of the subordinate bodies;
- d) oversee and intervene in the regulation of the working relations of pharmacists and their private subjects with the Ministry of Health and the Health Insurance Institute.

#### Article 14

1. Regional Councils are established according to the administrative territorial division.
2. The Regional Council elects the president and his/her deputy. The President is entitled to a four-year term, with the right of re-election.
3. The Regional Council shall appoint and remove the secretary.

#### Article 15

The Regional Council, under the supervision of the National Council and for the accomplishment of the mission of the Order of Pharmacists, shall have the following duties within its jurisdiction:

- a) oversees and intervenes in regulating working relations between pharmacists, various private pharmaceutical subjects and the inter-institutional ones in the regional health and pharmaceutical sector;
- b) manages the budget and all the properties of the regional Order of Pharmacists;
- c) implements the decisions of the National Council and the rules and instructions issued by the latter;
- ç) appoints the member registration commission.

#### Article 16

1. Disciplinary Commission shall function at the National Council and Regional Councils of the Order of Pharmacists, which are appointed by the General and Regional Assembly, respectively.
2. Disciplinary Commissions are bodies of professional adjudication, which shall verify and examine complaints against any violations of the Code of Pharmaceutical Deontology, as well as the technical errors of pharmacists in the course of practicing their profession.

3. Disciplinary Commissions which are attached at the regional councils exercise first-scale disciplinary powers. Their decisions are subject to appeal at the National Council disciplinary council, which exercises second-level disciplinary competencies.

#### Article 17

1. The disciplinary commission shall inquire and adjudicate, based on facts and evidence administered in a hearing. If the member is proved to have committed violations of the Code of Pharmaceutical Deontology or technical errors, the Commission shall decide on one of the following measures:

a) call of attention in writing;

b) call of attention with a note on file;

c) a fine from Lek 10,000 to 200,000;

ç) dismissal from the steering bodies of the Order of Pharmacists and withdrawal of the right to be re-elected in these bodies for a period up to three years;

d) removal from the Order of Pharmacists for a period up to three years.

2. The Commission has the right to decide to impose as a follow up measure on the violator the accomplished requalification at the public institutions, according the established fees.

3. The disciplinary measures referred to above shall be deemed as completed if, within one year from their imposition according to letters "a" and "b" of this article and, within 3 years according to letters "c" and "d", if no other disciplinary was imposed on the member of the Order of Pharmacists.

#### Article 18

1. Complaints against the decisions on disciplinary measures by the disciplinary commission of the regional council shall be submitted to the disciplinary commission of National Council of the Order of Pharmacists within 30 days from the notification of the decision in writing.

2. Upon 30 days from the receipt of the complaint, the disciplinary commission should come up with a decision on the submitted complaint. The decision of the disciplinary commission of the National Council is final.

3. With regard to the disciplinary measures referred to in letters "c" and "d" of Article 17 of this law, the person is entitled to go to the court within 30 days from the day of the notification of the decision in writing.

### CHAPTER III

#### TRANSITORY AND FINAL PROVISIONS

#### Article 19

1. The Minister of Health is tasked with the establishment of an ad-hoc commission, which should organize the first elections of the regional councils and of the National Council of the Order of Pharmacists.

2. These elections shall take place within 3 months from the entry of this law into force. The ad-hoc commission shall drop effect upon the election of the National Council.

#### Article 20

The Order of Pharmacists shall be funded by the state for a one-year period. The size and modalities of such funding shall be defined by sub-legal acts issued by the Council of Ministers.

#### Article 21

Any provision that falls contrary to this law is repealed.

#### Article 22

This law enters into force 15 days upon publication in the Official Gazette.

Ruled by Decree No.4010 of the President of the Republic of Albania, Alfred Moisiu dated 18.11.2003

## **Law 9323**

**No.9323, date 25.11.2004**

### **FOR DRUGS AND PHARMACEUTICAL SERVICES**

Based on Constitution's 78th and 83rd (first part) articles, and by the proposition of the Council of the Ministers,

THE PARLIAMENT OF THE REPUBLIC OF ALBANIA

DECIDED:

#### CHAPTER I GENERAL PROVISIONS

##### Article 1

###### Scope

This law defines the rules of production, importation, exportation, trading, prescribing, usage, quality control and inspection of actions related to drugs used by people in the Republic of Albania.

##### Article 2

###### Field of Action

This law regulates all subjects, legal and physical persons, owned by the state or privately held, citizens and foreign, whose activities are mentioned by the provisions of this law.

##### Article 3

###### Definitions

For the scope of this law, the terms mentioned below have the following meanings:

1. "Drugs": substances or combination of substances that carry healing and preventive properties for a disease, or are used for establishing a medical diagnosis. Known for their pharmacological, immunological, and metabolic actions, use of drugs in pre-established ways can reverse, correct, and modify the physiological functions of the human body.

2. "Pharmacopoeia": is the summary book of standards and rules, that under legal power defines the preparation, quality control and storage of the most important drugs used in the medical practice.

3. "Medical substances": also known as acting substances, are substances of natural origin (mineral, herbal, or animal), synthetic, obtained by the processes of fermentation and genetic technology, with a preset goal for the manufacturing of pharmaceutical products as carriers of pharmacological action.

4. "Side effect": is the undesirable or harmful response of the organism that has used a drug at normal doses for prophylaxis, diagnosis, curing a disease or for reversing, correcting and modifying a physiological function.



- 5 “Quality drug”: a drug is assessed as “quality drug” only if it complies with pharmacopoeia’s existing rules and standards, simultaneously warranting safety and efficacy in compliance with the purpose of its use.
6. “Pharmaceutical form” is considered the drug prepared according to certain technological, pharmaceutical processes in its most suitable form in order to be used by the patient (tablet, ampoule, suppository, etc.) and to preserve the acting effect within the time length of the declared warranty.
7. “Ready to use drug” is the drug submitted to all manufacturing, packaging, and final labeling processes.
8. “Manufacturing” is the whole activity that includes acquisition of the primary materials and substances, production, quality control, storage, marketing, distribution of the final product and all kinds of control of this activity.
9. “Herbal drug” is the drug that has one or more herbal acting substances, one or more herbal preparations, one or more such herbal substances combined with one or more herbal preparations.
10. “Good Manufacturing Practice” is the part of enterprise for quality assurance also indicated by the initials GMP, which assures that pharmaceutical products are continuously controlled along the manufacturing process, before they are launched to the market, according to the quality standards in compliance with the scope of their use and the requirements of the registration certificate.
11. “Quality Assurance” is a wide concept, which encompasses all the necessary measures to be taken for addressing problems that individually or together influence the quality of the pharmaceutical products, with the objective of maintaining standards in compliance with their use.
12. “Series” is a defined quantity of primary substances, packaging material or final product manufactured during one only process or some processes in a series that assures the homogeneity of the whole quantity.
13. “Clinical trial” is a systematic study on people for therapeutic discoveries or verifications, and/or side effects of medical products, and for studying their pharmacokinetics.
14. “Good Storage Practice” is the entity of rules that defines the conditions and requirements that should be met by the environment where primary substances, packaging material and final products are stored, so that the effect of physical factors (light, humidity and temperature), and that of microorganisms is minimal in order to assure stability and quality of drugs according to pharmacopoeia and approved standards.
15. “Pharmaceutical agency” is the retail unit where drugs are sold based on the drug list approved by the Minister of Health, according to the specifications defined by this law.
16. “Pharmacy” is the trade-health center where the preparation, packaging, quality control, sale and storage of drugs takes place according to the specifications defined by this law.
17. “Pharmaceutical formulary” is the summarizing manual, with legal authority, of the most common pharmaceutical preparations, that could be prepared in pharmacy and are known as official drugs.
18. “Standard” is the document where the norms of quality indicators, rules of sample taking for analysis, methods of analyses, rules of marketing, packaging, transportation, and storage of drugs, are described.

19. "Over the counter drugs" are the drugs used for self-medicating and sold in pharmacies without doctor's prescription.

20. "Registration certificate" is the certificate given when a drug is registered according to the specifications defined by this law.

21. "QKKB" is the Center for National Drug Control

22. "KNB" is the Commission of Drug Nomenclature

23. "Pharmaceutical importer" is the pharmaceutical trade unit that is supplied by foreign pharmaceutical manufacturers or wholesalers (authorized by the manufacturer) for realizing drug importation.

24. "Pharmaceutical exporter" is the pharmaceutical trade unit that is supplied by the Albanian and foreign manufacturers exercising activity within boundaries of the Republic of Albania realizing drug exportation.

25. "Pharmaceutical distributor" is the pharmaceutical trade unit that is supplied from the pharmaceutical importers and the manufacturers that exercise activity within the country to realize drug wholesaling.

26. "CIF price of import" is Cost, Insurance, Freight price defined for the drug by the manufacturer up to the customs point of entry in the Republic of Albania.

27. "Reimbursement List" is the list of drugs reimbursed by the Institution of Health Care Insurance.

#### Article 4

##### Prohibition of actions harmful to health

The manufacturing, sale, importation, exportation, prescription, and use of drugs that directly or indirectly harm or risk human health are forbidden.

#### Article 5

##### Veterinary drugs

The manufacturing, importation, exportation, sale, control and use of veterinary drugs are performed according to the existing laws for the veterinary practice.

## CHAPTER 2

### DRUG MANUFACTURING

#### Article 6

##### Practices of Manufacturing

I. The drug manufacturing in the Republic of Albania is done in compliance with the provisions of this law, good manufacturing practice and Albanian legislation for environment protection.

2. Good Manufacturing Practice (GMP) is approved by the Minister of Health and is obligatory for all drug manufacturers

3. The manufacturers who are currently exercising this activity, have a 2-year time from the time this law enters into force to meet the standards of GMP.

#### Article 7

##### Licensing

Legal persons, citizens or foreign, that exercise activity in the field of drug manufacturing, are licensed by the Minister of Health in compliance with Albanian legislation in force and ratified regional and international trade agreements.

#### Article 8

##### Manufacturing in the country

1. Drugs can be manufactured in the country by legal persons, licensed only after receiving appropriate authorization by the Minister of Health, in accordance with the proposition of the Good Manufacturing Practice Verification Commission.

2. Manufacturing of drugs intended for exportation abides by all regulations, as do manufactured drugs intended for the Albanian market.

3. Good Manufacturing Practice Verification Commission is organized with the order of Minister of Health, and works in compliance with the regulation approved by him.

4. The Minister of Health approves the regulation where conditions of manufacturing, necessary documentation, and standards to be met, as well as the time-length of manufacturing authorization, are specified.

#### Article 9

##### Change of manufacturing conditions

The change of manufacturing conditions is done with the authorization of Minister of Health, according to the same regulations for the manufacturing authorization.

#### Article 10

##### Drugs prepared in pharmacy

1. No specific authorization is needed for drugs prepared in pharmacy according to the pharmaceutical formulary and doctor's prescription.

2. The pharmaceutical formulary is approved by the Minister of Health.

## CHAPTER 3

### REGISTRATION

#### Article 11

##### Drug circulation

1. Drugs circulating in the Republic of Albania should be registered, with exception of drugs prepared in pharmacy according to doctor's prescription and pharmaceutical formulary.
2. In case of emergency (natural catastrophes, epidemics) or in case of health service needs (the sole drug alternatives for ambulatory and hospital medication), the Minister of Health authorizes importation of unregistered drugs, according to regulations defined by the Council of Ministers.

#### Article 12

##### QKKB and KNB

1. The Center of National Drug Control (QKKB) is a specialized institution for drug analyses, registration, and control, and inspection of activities in the pharmaceutical field.
2. QKKB functions with a special status. Its organization, structure and method of functioning are regulated by the Council of Ministers.
3. Drug Nomenclature Commission (KNB) is an advisory organ of the Minister of Health. Its structure, organization and method of functioning are regulated by order of the Minister of Health.

#### Article 13

##### Application and Registration Practice

1. Drug application and registration are done by the license holder, even when he is not the drug manufacturer in the QKKB, according to the regulation approved by the Minister of Health.
2. QKKB accepts for registration:
  - a. Drugs manufactured in our country, and those registered and circulating in one of the European Union countries, Switzerland, USA, Canada, Japan and Australia;
  - b. Drugs manufactured in Balkan countries, only when are registered and have circulated in their countries for no less than 2 years.
3. Drug registration is done in QKKB in accordance with the regulation approved by the Minister of Health.
4. Drugs are registered only when they meet the criteria for effectiveness and safety in compliance with the purpose of their use.

#### Article 14

##### Registration Certificate

1. The Minister of Health, based on the proposal of QKKB and KNB, orders registration of the drug.
2. After issuance of registration order, QKKB issues the respective registration certificate after payment of the respective fee is made, no later than 2 months.
3. Registration certificate is valid for 5 years from the issue date of Minister's order. This period may be extended through registration procedure after request submission.

#### Article 15

##### Re-registration

1. The drug is re-registered after completion of requested documentation and payment of the necessary fee.
2. Rules for re-registration, as well as, the elements of registration certificate are defined by the Minister of Health.
3. Registration and re-registration fees are determined by the Minister of Health.

#### Article 16

##### Deregistration

The Minister of Health, with the proposal of QKKB, orders deregistration of a drug if:

- a) drug does not have the quality, safety, and efficacy declared in the registration certificate;
- b) drug does not meet the current standards for quality, safety, and efficacy;
- c) displays harmful effects when used, even when used in compliance with accurate instructions

## Article 17

### Accelerated procedure of registration

Drugs that registered by the European Medicine Agency (EMA), Food and drug Administration and drugs of the countries with which respective agreements exist, are registered according to this law's provisions, but with an accelerated procedure by order of the Minister of Health.

## Article 18

### Publication of Drug Registry

1. QKKB prepares and publishes periodically, each year, the drug registry with respective prices and updates it every month.
2. QKKB is obligated to immediately notify the pharmaceutical subjects for every newly registered drug, and every unregistered drug that is imported with a special authorization.

## CHAPTER 4

### LAUNCHING THE DRUGS TO MARKET

## Article 19

### Permission of use

1. QKKB permits launching of drugs to market through permission of use of registered drugs and unregistered drugs imported with special authorization, according to article 11, part 2.
2. Rules of granting permission of use are approved by the Minister of Health.

## Article 20

### Stamp of Control

1. All drugs launched to market must have the stamp of control distributed by the QKKB, as well as their retail price.
2. The elements of the stamp of control and the procedures of manufacturing, distribution and printing are defined by the Council of Ministers.

## Article 21

### Donated drugs, promotional and hospital samples

The marketing of donated drugs, promotional and hospital samples that carry their distinct sign in compliance with the purpose of their use is forbidden.

## CHAPTER 5

### CLINICAL TRIALS AND PROTECTION OF PEOPLE DURING CLINICAL TRIALS

## Article 22

## Clinical trials

1. Clinical trials with drugs are performed on people only if they are considered as necessary:
  - a) for granting permission of registration;
  - b) proving the clinical effect and safety of a drug in the process of scientific research;
  - c) Re-evaluating the efficacy and safety of a drug after its introduction to market.
2. Clinical trials are performed in health institutions officially recognized by the Ministry of Health, in accordance with the standards of good clinical practice approved also by the Minister of Health.
3. Performing clinical trials on people without informing them and without their written consent is forbidden.

## Article 23

### Authorization for clinical trials

1. Authorization for performing clinical trials on people with unregistered drugs is granted by the National Committee of Ethics after approval from the scientific board of the institution that carries out the study, QKKB and KNB.
2. Organization of structure and method of functioning of the committees of ethics are determined by the Council of Ministers.

## CHAPTER 6

### DRUG WHOLESALING

## Article 24

### Drug wholesaling

1. Every legal or physical person, citizen or foreign, can exercise activity as a pharmaceutical distributor only after obtaining a license from the Commission of Licenses of Ministry of Health.
2. The Minister of Health determines the structure of this Commission and approves the regulation of its functioning and defines the method of compensation for its members.
3. A pharmaceutical distributor may wholesale medicating materials, accessories, hygienic-cosmetic and dietetic articles.

## Article 25

### Licensing

1. Licensing of legal or physical persons for drug wholesaling is made according to the license of technical director, who is a licensed pharmacist with more than 2 -year experience in the pharmaceutical sector.
2. License is given for a 5-year period, and after this period the license is given for a 10-year period.

3. The technical director is responsible for all technical and professional activities that the respective distributor engages in.

#### Article 26

##### Good storage and distribution practices

1. The conditions and equipments of the importer, exporter and pharmaceutical distributor should be in compliance with good storage and distribution practices of the drug according to pharmaceutical standards.

2. Good storage and distribution practices are approved by the Minister of Health and it is obligatory that they are respected by importers, distributors and pharmacies.

#### Article 27

##### Wholesaling and accompanying documentation

1. Drug wholesaling is performed in presence of the technical director or the employed pharmacist.

2. Drug wholesaling is made with a receipt and is accompanied with the respective documentation, the form and elements of which are determined with order of the Minister of Health and Minister of Finance.

3. Retail selling of drugs by the importer and pharmaceutical distributors is forbidden.

#### Article 28

##### Reporting activities

Citizen manufacturers, importers and pharmaceutical distributors periodically submit information to QKKB about their activities.



## Article 29

### Marketing and exportation from resident manufacturers

1. Resident manufacturers sell their products only to pharmaceutical distributors and export them to foreign countries.
2. Drugs manufactured in the country and intended only for export are allowed to be traded to other countries without being registered in our country.

## CHAPTER 7

### Retail selling

## Article 30

### Pharmacies and pharmaceutical agencies

1. Only pharmacies and pharmaceutical agencies can sell at retail according to provisions of this law.
2. Pharmacies open in urban areas, in a distance of 100-150m from each other, depending on the density of the population, one for every three thousand residents.
3. Pharmacies can be private or public.
4. There can be performed tests in pharmacies, such as pregnancy test, blood sugar test, blood pressure, weight and height measurements.

## Article 31

### Technical director of pharmacy

The function of the technical director of pharmacy can be performed by every citizen of the Republic of Albania and every foreign citizen that meets the following conditions:

- a) is a pharmacy university graduate;
- b) has a work experience of 3 years;
- c) is a member of the Order of Pharmacists.

## Article 32

### Licensing

1. License of technical director is initially given for a 5-year period, and after this period it is given per a 10-year period.
2. Pharmacy and pharmaceutical agency licensing criteria are determined by the Council of Ministers.
3. The technical director of the pharmacy is the licensed pharmacist only for one pharmacy, and cannot engage in any other activities in the pharmaceutical service.

### Article 33

#### Exercising of the activity

The pharmacy exercises its own activity only in presence of the technical director or the pharmacists employed with a job contract.

### Article 34

#### Other pharmaceutical personnel

In pharmacy there can be employed pharmacists and assistant-pharmacists with a job contract; they do not have license, but have to be registered in QKKB.

### Article 35

#### Pharmaceutical agency

In the rural areas, where there is no pharmacy, there can be opened pharmaceutical agencies, with a technical director as assistant-pharmacist.

### Article 36

#### Prescription

1. Sale of drugs in pharmacy or pharmaceutical agency without doctor's prescription is forbidden, unless they are OTC drugs according to a list approved by the Minister of Health.

2. Prescriptions executed in pharmacy are kept in pharmacy as follows:

- a. 2 years for the common prescriptions;
- b. 3 years for narcotic and psychotropic drugs;
- c. 5 years for poisonous drugs with strong action.

3. In pharmacy can be sold medicating materials, accessories, hygienic-cosmetic and dietetic articles.

### Article 37

#### Obligatory literature

Pharmacies and pharmaceutical agencies are obliged to maintain updated literature:

pharmaceutical legislation, drug registry, reimbursement list, pharmaceutical formulary, drug formulary and therapeutic formulary.

### Article 38

#### Working hours

Working hours of pharmacies and pharmaceutical agencies during holidays and celebrations is determined by the organs of the local administration, in collaboration with the Order of Pharmacists and other professional organization of pharmacists.

#### Article 39

##### Night shift pharmacy

Night shift pharmacy service in large urban centers is assured through one or more pharmacies on rotation as defined by the Ministry of Health.

#### Article 40

##### Restrictions for medical doctors and dentists

1. Storage and preparation of drugs for sale by doctors and dentists is forbidden.
2. Doctors and dentists store and use in their clinics drugs in quantities and kinds sufficient for first aid or for necessary procedures related to professional activities according to the specifications made in the list approved by the Minister of Health.

#### Article 41

##### Drug prescribing and giving prescription

With instructions of the Minister of Health, persons with medical qualifications are determined so that they are allowed to prescribe drugs and give prescriptions, and rules of drug prescriptions are determined, as well.

#### Article 42

##### Teaching practices

Pharmacies are obliged to accept students for carrying out professional teaching practice, according to a mutual contract between the pharmacy and the School of Medicine.

#### Article 43

##### Drugs used by humans and veterinary pharmacies

1. The preparation, modification, and trading of drugs used by humans in the veterinary pharmacies and pharmaceutical agencies, is forbidden.
2. Drugs used by humans, that can also be used on animals, are sold only in depots and pharmacies determined by this law.

#### Article 44

##### The emblem

The emblem of pharmacies and pharmaceutical agencies is the same, a glass vessel with a globular base tapering to a narrow neck, and a snake. The form, size and color are determined by order of the Minister of Health.

## Article 45

### List of the obligatory drugs

List of obligatory drugs for pharmacies and pharmaceutical agencies in order to meet the needs of pharmaceutical services, is determined by order of the Minister of Health.

## CHAPTER 8

### IMPORTATION AND EXPORTATION OF DRUGS

## Article 46

### Licensing of import-exportation activity

1. Every legal or physical person, citizen or foreign, can exercise activity of import-exportation in the field of wholesale or retail sale of drugs and/or their primary medical substances, only after obtaining from the Commission of Licenses at the Ministry of Health, the professional license for the technical director, who is a pharmacist with at least 2-year work experience in the professional field.

2. Professional licenses for importation and exportation of drugs are granted according to criteria determined by the Council of Minister.

## Article 47

### Authorization for registered drug importation

1. Registered drugs importation is performed based on the drug registry and importation authorization issued by the QKKB.

2. Criteria of authorization granting and its elements are determined by the Minister of Health.

## Article 48

### Authorization for unregistered drug importation

1. Importation of unregistered drugs is made with special authorization of the Minister of Health.

2. Donated drug importation is done with special authorization of the Director of the Pharmaceutical Directory in the Ministry of Health for every series.

3. Criteria of authorization granting and its elements are determined by the Council of Ministers.

## Article 49

### Importation of the primary and supplementary substances

1. Importation of primary, supplementary, packaging and reagent substances etc., which are used in the process of drug manufacturing, can be done by the distributors and/or manufacturers themselves with special authorization for every series.

2. Criteria of authorization granting and its elements are determined by the Minister of Health.

## CHAPTER 9

### DRUG PRICES

#### Article 50

##### Drug prices and margins

1. The price of drugs in the market is controlled and based on CIF prices of the import and on the manufacturing prices for the drugs produced in the country.
2. The price control of drugs in the market is realized through margins of manufacturing and trading as determined by Council of Ministers.
3. Prices of reimbursement list are determined by the Council of Ministers.

#### Article 51

##### Commission of Drug Prices

1. Council of Ministers creates the Commission of Drug Prices made of:
  - 2 representatives from Ministry of Health;
  - 2 representatives from Ministry of Finance;
  - 1 representative from Ministry of Economy, Trade and Energy;
  - 2 representatives from Institution of Health Care Insurance.
2. Method of functioning of this Commission is determined by the Council of Ministers, with the proposal of the Ministers of Finance and the Minister of Health.

## CHAPTER 10

### DRUG ADVERTISING

#### Article 52

##### Drug advertising and promotion

1. Advertising and tools of massive information are allowed only for OTC drugs, meanwhile promotion for other drugs can be made only through literature or scientific professional activities.
2. Rules for advertising and promotion are approved by Minister of Health.

#### Article 53

##### Restrictions to advertising

1. Advertising of drugs for medicating effects that have not been declared at the time of registration, as well as concealing known counter indications and side effects is forbidden.

2. Advertising of substances not recognized as drugs by this law, is forbidden.

## CHAPTER II

### DRUG CONTROL

#### Article 54

##### Activity control

1. QKKB is responsible for the control of any activity in the pharmaceutical field.

This center exerts control on:

- a) activities of manufacturing, environment and equipments used for drug manufacturing;
- b) wholesale and retail sale of drugs, as well as drug storage conditions;
- c) primary medical and supplementary substances, and package material;
- d) Drugs imported by all licensed subjects according to the provisions of this law.

2. In order to execute these responsibilities, QKKB collaborates with:

- a. Structures of hygiene and epidemiology in the primary care;
- b. Public Health Institute;
- c. Authorities of State Police;
- d. Customs and Tax Authorities;
- e. Veterinary Inspectorate;
- f. Environment Inspectorate.

3. Methods of control and collaboration are determined by the Council of Ministers.

#### Article 55

##### Veterinary drug control

QKKB in collaboration with the Veterinary State Control Laboratory controls the drugs used on animals, the products of which (meat, milk, egg) are used as food by people.

#### Article 56

##### Supervision and control

1. Minister of Health, through the Pharmaceutical Directory, exerts regular control over the activities of QKKB for the execution of its duties and responsibilities.

2. Rules of supervision are determined by the Council of Ministers.

## CHAPTER 12

### ADMINISTRATIVE VIOLATIONS

#### Article 57

##### Administrative violations

I. When the violations below do not constitute penal offences, they constitute administrative violation and are punishable by pharmaceutical inspectors as below:

- a) Violation of article 8 part I and article 9, drug manufacturing without respective authorization and change of pharmaceutical form without authorization are punishable by drug sequestration, license suspension and suspension from the technical director position;
- b) Violation of article 19, launching to market registered drugs without permission of use and launching to market unregistered drugs without special authorization is punishable by drug sequestration and license suspension;
- c) Violation of article 20 part I, wholesale trading of drugs without the stamp of control and the wholesale price is punishable by license suspension;
- d) retail sale of drugs without the stamp of control and retail price is punishable by drug sequestration and license suspension for no less than 2 years;
- e) Violation of article 21, sale of donated drugs and that of promotional and hospital samples is punishable by license sequestration and suspension;
- f) Violation of article 26 part I, disregard toward good storage and distribution practices is punishable by a fine of 200 thousand lek, and recurring violation is punishable by license suspension;
- g) Violation of article 27, wholesale of drugs in absence of the technical director or pharmacist is punishable by a fine of 20 thousand lek; wholesale of drugs without the accompanying receipt and documentation is punishable by a fine of 100 thousand lek; retail sale of drugs by importers or their distributors is punishable by a fine of 50 thousand lek;
- h) Violation of article 28, withholding periodic information from pharmaceutical subjects is punishable by a fine of 50 thousand lek, and recurring violation is punishable by license suspension;
- i) Violation of article 33, retail sale of drugs in a pharmacy by people with no pharmacy degree is punishable by license suspension; retail sale by assistant-pharmacist in absence of the technical director or the pharmacist is punishable by a fine of 50 thousand lek and in case of recurring violation, it is punishable by license suspension;
- j) Violation of article 36 part I, sale of drugs in pharmacy or pharmaceutical agency without doctor's prescription, - except OTC drugs, is punishable by a fine of 50 thousand lek, and in case of recurring violation, it is punishable by license suspension;
- k) Violation of article 40 part I, preparation and distribution of drugs by doctors and dentists is punishable by an amount equaling 10 times the drugs value;

l) Violation of article 43 part I, sale of drugs used by humans in the veterinary pharmacies is punishable by a fine of 10 thousand lek and a proposal for license suspension to the Minister of Agriculture, Food and Consumer Protection;

m) Violation of article 45, absence of obligatory drugs in pharmacy or pharmaceutical agency is punishable by a fine of 10 thousand lek;

n) Violation of article 49, importation of primary and supplementary substances without respective authorization is punishable by an amount of 10 times the drugs value, their sequestration, and in case of recurring violation it is punishable by license suspension;

o) Violation of article 59, false declaration of CIF importation prices and prices of drugs manufactured in the country is punishable by a fine equal to the 100% of the sum of declared value and the real price; sale at prices different from those determined by the Commission of Drug Prices is punishable by a fine equal to the 100% of the unjust profit and, in case of recurring violation, it is punishable by license suspension;

p) Violation of articles 52 and 53, non-OTC drug advertising against the drug advertising and promotion regulation, is punishable by a fine of 100 thousand lek, and in case of recurring violation it is punishable by license suspension.

2. Violation of provisions specified in articles 7, 24 part I, 32 and 46, drug manufacturing with no license, drug wholesale with no license, drug retail sale with no license and import-exportation of drugs with no license, respectively, when do not constitute penal offence are punishable by drug sequestration.



## **Law No. 9523, dated 29.4.2006**

### **ON SOME CHANGES TO LAW NO. 9323, DATED 25.11.2004, “ON DRUGS AND PHARMACEUTICAL SERVICE”**

Pursuant to Articles 78 and 83, item 1, of the Constitution, upon proposal of the Council of Ministers,  
THE ASSEMBLY OF THE REPUBLIC OF ALBANIA

DECIDED:

The following changes shall be made to Law 9323, dated 25.11.2004, “On Drugs and Pharmaceutical Service”:

Article 1

Item 2 of Article 13 shall change as below:

“2. DCDC shall admit for registration:

- a. the drugs manufactured in Albania, as well as the drugs registered and traded in one of the European Union countries, Switzerland, US, Canada, Japan and Australia;
- b. the drugs manufactures in the Balkans countries, only in those cases where they have been registered and traded in their country from no less than two years.”.

Article 2

Article 57 shall change as below:

“Article 57

Administrative contraventions

1. The following violations, unless they constitute a criminal offence, shall be considered administrative contraventions and subject to penalty by the pharmaceutical inspectors, as below:

- a) violation of Article 8, items 1 and 2, and of Article 9 on drug manufacturing without the relevant permit and alteration of the pharmaceutical form without permit shall be penalized with seizure of drugs and withdrawal of the license to of activity and of the technical administrator;
- b) violation of Article 19, on trading registered drugs without the permit of use and of the unregistered drugs without special authorization and permit of use, shall be penalized with seizure of drugs and withdrawal of the license;
- c) violation of Article 20, item 1, the wholesale trading of drugs without the control stamp and the retail price, shall be penalized with license withdrawal;
- ç) retail selling of the drugs without the control stamp and the retail price shall be penalized with license withdrawal for a period of at least two years;

d) violation of Article 21, trading of donated drugs and promotional and hospital sample, shall be penalized by seizure and license withdrawal; dh. violation of Article 26, item 1, failure to observe good storage and distribution practices, shall be penalized by a fine of Lek 200,000 and, when recurring, by withdrawal of the license.

e) violation of Article 27, wholesale marketing of drugs in absence of the technical administrator or the pharmacist, shall be subject to a fine of Lek 20,000; wholesale trading without the respective invoice and the relevant documentation shall be penalized by a fine of Lek 100,000; retail selling of drugs by their importers or distributors shall be fined with Lek 50,000;

ë) violation of Article 28, failure of periodical reporting by pharmaceutical subjects, shall be penalized by a fine of Lek 50,000 and, in case of recurrence, by license withdrawal;

f) violation of Article 33, drug retail selling in pharmacies from individuals without pharmaceutical education, shall be subject to license withdrawal; drug trading by the assistant pharmacists in absence of the technical administrator or the pharmacist, shall be penalized with a fine of Lek 50,000 and, in case of recurrence, with the license withdrawal.

g) violation of Article 36, item 1, drug trading in pharmacies or pharmaceutical agencies without medical prescription, except for OTC drugs, shall be penalized with a fine of Lek 50,000 and, in case of recurrence, with license withdrawal;

gj) violation of Article 40, item 1, preparation and distribution of drugs by doctors and dentist, shall be subject to a fine that amounts up to ten times of their value;

h) violation of Article 43, item 1, trading of drugs used by people in veterinarian pharmacies, shall be fined with Lek 10,000, whereas a proposal for license withdrawal shall be submitted to the Minister of Agriculture, Food and Consumer Protection;

i) violation of Article 45, lack of mandatory drugs in pharmacies and pharmaceutical agencies, shall be subject to a fine of Lek 10,000;

j) violation of Article 49, importation of pharmaceutical supplementary and raw material without the respective authorization shall be subject to a fine amounting to ten times their value, seizure and, in case of recurrence, to license withdrawal;

k) violation of Article 50, trade with prices that are different from those established by the Decision of the Council of Ministers, shall be subject to a fine amounting up to ten times of their value and, in case of recurrence, to license withdrawal;

l) violation of Articles 52 and 53, advertising of non-OTC drugs, against the regulation on advertising and promotion, shall be punished with a fine of lek 100,000 and, in case of recurrence, with license withdrawal.

2. Violation of the provisions defined in Articles 7, 24 item 1, 32 and 46, drug manufacturing without license, wholesale drug trading without license, retail drug trading without license and drug import-export without license, respectively, if not criminal offences, shall be subject to drug seizure.

### Article 3

This law enters into force 15 days upon publication in the Official Gazette.

Ruled by Decree No. 4865 of the President of the Republic of Albania, dated 10.05.2006.

ALFRED MOISIU

## **Law\_9644, drug pricing amendments to Law 9323**

### **LAW No .9644, dated 20.11.2006**

#### **On Some Changes and Additions to Law No. 9323, Dated 25.11.2004, “On Drugs and Pharmaceutical Service,” Amended**

Pursuant to Articles 78 and 83, item 1 of the Constitution, upon proposal of the Council of Ministers

THE ASSEMBLY OF THE REPUBLIC OF ALBANIA

DECIDED:

The following changes and additions shall be made to Law 9323, dated 25.11.2004, “On Drugs and Pharmaceutical Service”:

Article 1

Items 26 and 27 shall be added to Article 3, with the following content:

26. “Import CIF cost” is the Cost, Insurance, Freight cost calculated by the manufacturer for the drug up to the moment of entry into the customs point of the Republic of Albania.

27. “Reimbursement list” is the list of the drugs reimbursed by the Health Insurance Institute. Article 2

Article 50 shall change as below:

Drug pricing and margins:

1. The market price of drugs shall be controlled by and based on the import CIF cost and, for the drugs manufactured in the country, it shall be calculated on the manufacturing cost.
2. Drug prices in the market shall be controlled through the manufacturing and marketing margins, which are established by the Council of Ministers.
3. Prices of the drugs included in the reimbursement list shall be established by a Decision of the Council of Ministers.

Article 3

Article 51

Drug Pricing Commission

1. The Council of Minister shall establish the Drug
  - 2 representatives of the Ministry of Health
  - 2 representatives of the Ministry of Finance
  - 1 representative of the Ministry of Economy, Trade and Energy

- 2 representatives of the Health Insurance Institute

2. The functioning modalities of this Commission shall be defined by a Decision of the Council of Ministers, upon proposal of the Minister of Finance and Minister of Health.”

#### Article 4

Letter “k” of Article 57 shall be changed as below:

k) violation of Article 50, the counterfeit declaration of the import CIF cost and of the manufacturing prices of the drugs manufactured in the country, shall be penalized by a fine equivalent to 100% of the calculated amount (difference) between the declared value and the real price.

Trading with prices which differ from those established by the Drug Pricing Commission shall be punished with 100% of the unjust profit amount and, in case of recurrence, with the license withdrawal.

#### Article 5

This law enters into force 15 days upon publication in the Official Gazette.

Ruled by Decree No. 5149 of the President of the Republic of Albania, dated 12.12.2006.

ALFRED MOISIU

## **Law 10008**

**Law No. 10 008, dated 27.10.2008**

### **ON SOME CHANGES AND ADDITIONS TO LAW 9323, DATED 25.11.2004, “ON DRUGS AND PHARMACEUTICAL SERVICE,” AMENDED**

Pursuant to Articles 78 and 83, item 1, of the Constitution, upon proposal of the Council of Ministers,

THE ASSEMBLY

OF

THE REPUBLIC OF ALBANIA

DECIDED:

The following changes and additions shall be made to Law 9323, dated 25.11.2004, “On Drugs and Pharmaceutical Service,” amended:

Article 1

Items 28 and 29 are added to Article 3, “Definitions”, with the following content

28. “Regional Public Health Directorate (hereafter referred to as “regional PHD”) is the authority which coordinates, runs and monitors all the healthcare service at the regional level through the pharmaceutical structures, which are composed of pharmacists.

29. “Pharmacist” is the practitioner, who holds a degree in pharmacy, entailing a unique 5-year cycle (Integrated Diploma of the Second Level). Equally recognized shall be also the diplomas issued by the University of Tirana, Faculty of Pharmacy, according to the prior curricula approved by the Ministry of Education and Science, as well as the foreign degrees recognized by this Ministry. Article 2

Article 17 shall change as below:

Accelerated registration procedure

“The registration of the drugs already registered with the European Medicine Evaluation Agency (EMA), with the US Food and Drug Administration (FDA), in Australia, Canada and Switzerland, as well as the drugs registered in compliance with the communitarian procedures in the European Union, shall be automatically registered within 30 working days, upon verification of the authenticity of the submitted documents.”

Article 3

Article 18 shall change as below:

“Article 18

Publication of drug register

1. NCDC prepares and publishes on an annual basis the drug register containing the respective prices and the name of the importers authorized by the trade license holder companies or by the manufacturing companies on an annual basis and updates it on a monthly basis.
2. NCDC should submit the drug register and its updates to the Customs General department.
3. NCDC should notify immediately the pharmaceutical subjects and the Customs General Department on any registered and unregistered drug, as well as on any unregistered drug that is imported upon special authorization.

#### Article 4

Article 20 shall change as below:

“Article 20

#### Control stamp

1. All the marketed drugs should have on them the control stamp distributed by NCDC, as well as the retail price.
2. The control stamp should be double and contain at least the following elements:
  - a) drug name and dosage
  - b) drug retail price
  - c) the name of the authorized importer
3. The other elements of the control stamp and the other production and stamping procedures shall be established by a Decision of the Council of Ministers.”

#### Article 5

Article 24 shall change as below:

#### Drug wholesale

1. The drug wholesale activity shall be exercised by legal persons, Albanian or foreigners, who are equipped with a license issued exclusively by the Ministry of Health.
2. In order to start the above activity, the interested subject shall declare upon his/her own responsibility to meet all the requirements provided for by the applicable law on this purpose.
3. The Regional PHD shall verify the data submitted by the subject within 20 working days.
4. If this authority provides no answer upon expiration of such timeline, the Pharmaceutical Department at the Ministry of Health shall send the procedure for action to the National Centre for Drug Control, which shall come up with a response within 10 working days.
5. Upon receipt of the inspection report issued by responsible PHD or DCDC, the Ministry of Health should issue license within 10 working days. The subject shall retrieve the license at the regional PHD offices.

6. The pharmaceutical distributor should have a pharmacist as a technical administrator.
7. The technical administrator and the recruited pharmacists shall be registered with the regional PHD.
8. The subject licensed to exercise the drug wholesale trading activity may also exercise the wholesale trade of the medical devices, accessories, as well as other hygiene, cosmetic and dietetic items.
9. The approval criteria and procedures of the activity, as well as the self-declaration modalities, shall be defined by a Decision of the Council of Ministers.”

#### Article 6

Article 25 is changed as below:

“Article 25

Technical administrator of pharmaceutical distributor

Technical administrator of the pharmaceutical importer, exporter and distributor shall be a pharmacist who is member of the Order of Pharmacists of Albania, with two years of working experience in the pharmaceutical sector, and who shall be responsible of the entire technical and professional activity exercised by the respective subject.”.

#### Article 7

Article 31, letter “b” shall change as below:

“b) has two years of working experience;”.

#### Article 6

Article 32 shall change as below:

#### Article 32

Pharmacy

1. The activity of a pharmacy may be exercised by all the natural and legal persons, Albanian or foreigners, who are licensed by the regional PHD.
2. In order to start the activity referred to above, the interested subject shall declare under his own responsibility that he meets all the requirements provided for by the applicable legislation for this purpose.
3. False declaration shall constitute a motive deny the license to the subject for a 5-year period.
4. The regional PHD shall verify the documents submitted by the subject within 20 working days.
5. If, upon expiration of this timeline, no answer is provided by this authority, the activity shall be considered as approved.
6. The regional PHD should notify DCDC on a periodical basis, within 10 working days, on any new pharmacy opened in its territory.



7. DCDC shall inspect the new activity within 5 working days upon receipt of the notification.
8. The pharmacy shall be allowed to exercise the activity only in the presence of the technical administrator or the employed pharmacist.
9. The technical administrator of the pharmacy is licensed only for one pharmacy.
10. The technical administrator and the employed pharmacists should register with PHD.
11. Approval terms and procedures of the activity, as well as the self-declaration modalities shall be defined by a Decision of the Council of Ministers.”

#### Article 9

Articles 33 and 34 are repealed.

#### Article 10

Article 35 shall change as below:

#### “Article 35

##### Pharmaceutical agency

1. When no drugstore exists in the rural areas, pharmaceutical agencies shall be established, with an assistant pharmacist as the technical administrator, based on the declaration of the latter on meeting the required criteria.
2. The beginning of the drug trading activity at the pharmaceutical agency shall be based on the procedure provided for by Article 32 of this law.
3. The pharmaceutical agency shall engage in retail selling of drugs, based on the list approved by the Ministry of Health.”

#### Article 11

Article 46 shall change as below

#### “Article 46

##### Drug import-export activity

1. Any legal or natural person, Albanian or foreigner, may exercise the drug import-export activity, only upon issuance of the professional license to the technical pharmacist administrator, who has with 2 years of working experience in the sector.
2. The subject shall follow the procedures provided for by Article 24 of the law to obtain the license.”

#### Article 12

Article 47 shall change as below:

#### “Article 47

## Import of registered drugs

1. Drugs registered in the Republic of Albania shall be imported by the importers who are authorized by the trade license holder companies or manufacturing companies, in accordance with the published drug register, provided for by Article 18 of this law,
2. The import procedure shall be carried out at the entry customs offices, in the presence of the pharmaceutical inspector.

## Article 13

Article 58 shall change as below:

“Article 58

## Suspension of approved activities, license withdrawal and freezing and seizure of drugs

1. When the pharmaceutical inspectors identify administrative contraventions, in accordance with Article 57 of this law, they suggest to the regional PHD to and notify the Ministry of Health on:
  - a. the suspension of the activity;
  - b. withdrawal of the license.
2. The pharmaceutical inspectors shall freeze and seize the drugs in case of identified violations, as provided for by this law.”

## Article 14

Article 59 shall change as below:

“Article 59

## Administration and destruction of seized drugs

1. Seized drugs with valid use and regular documents shall pass under the administration of the Ministry of Health.
2. Seized and confiscated drugs that are not valid for use shall be destroyed in the presence of pharmaceutical inspectors, through a regular process verbal, in accordance with the modalities defined in the legislation on the environment protection, at the expenses of the infringing subject.”.

## Article 15

This law enters into force 15 days upon publication in the Official Gazette.

SPEAKER OF THE ASSEMBLY

JOZEFINA TOPALLI (COBA)

## **COM 182**

### **DECISION**

#### **NO. 182, DATED 25.4.1995**

#### **ON DRUG MARKETING PRICES**

Based on the Law No. 7815, dated 20.4.1994, "On Drugs" and on Law No. 7870, dated 13.10.1994, "On Health Insurance in the Republic of Albania," upon the proposal of the Ministry of Health and Environmental Protection, the Council of Ministers

#### **DECIDED**

1. The maximum drug marketing price limit to be set by businessmen shall be established up to 15% over the initial purchase price CIF, converted in money based on the respective daily exchange rate, which is announced by the Bank of Albania. The maximum wholesale price margin of drugs from domestic manufacturers shall be set up to 20% over the manufacturing cost.
2. The maximum margin of retail prices of drugs from the open network, upon the proposal of the drug pricing commission, shall be setup to 35% over the purchase price, which is calculated after the added margin provided for by item 1 of this decision.
3. The drug price structure of the main list for the effect of reimbursement shall be approved by the Minister of Health and Environmental Protection, upon the proposal of the Health Insurance Institute.
4. Selling and reference prices of the drugs which are part of the main list shall constitute the maximum margins for the calculation of the price reimbursement size of the drugs included in this list and are mandatory for implementation by all the open pharmacies. Pharmacies shall post drug selling prices in visible places, according to the names of the main list, as well as the list of basic drugs.
5. The drug list shall be approved according to the list attached with this decision.
6. The Health Insurance Institute shall reimburse with 100 % the prescriptions on essential drugs for children of 0-12 months of age, war invalids, for the invalids of the 1st and 2nd group on diseases that have caused their disability. The Ministry of Health and Environmental Protection establishes the list of essential drugs, which are necessary to tuberculosis and carcinoma treatment.
7. Health Insurance Institute is entitled to make changes to the price structure of the main list drugs during the year, according to item 3 of this decision.
8. With the implementation of this law is charged the Ministry of Health and Consumer Protection and the Health Insurance Institute.
9. The Decisions No. 17 of the Council of Ministers, dated 24.1.1994, "On Changing Drug Retail Prices and Setting of Maximum Selling Margins by Private Subjects," No. 525, dated 17.10.1994, "On State Subsidy for Essential Drugs," No.51, dated 23.1.1959, item 3, "On Measures to Further Reduction of Mortality Rate among Infants," No. 83, item 2, dated 16.3.1983, "On Reduction of Retail Prices for Some Domestic and Imported drugs, No. 247, dated 27.5.1993, "On Partial State Subsidy of Invoices of Expenditure on Pharmaceuticals for Invalid Treatment," are repealed.

This decision enters immediately into force.

PRIME MINISTER

ALEXANDER MEKSI

**REPUBLIC OF ALBANIA**

**Council of Ministers**

**DECISION**

**No. 56, dated 28.01.2005**

**ON CALCULATION OF DRUGS PRODUCTION AND MARKETING MARGIN**

Pursuant to Article 100 of the Constitution and Article 44 of the Law No. 7815, dated 20.4.1999, "On Drugs", amended by proposal of the Minister of Health, the Council of Ministers

**DECIDED**

1. The maximum limit of the drugs selling price by domestic producers shall be established by calculating a margin of 20 percent over the production cost.
2. The maximum wholesale price limit of imported drugs by pharmaceutical importers and distributors shall be established by calculating a margin of up to 18 per cent over the CIF price in Lek, converted according to the average exchange rate as published by the Bank of Albania on a semester basis. For the drugs of domestic production, such limit shall be calculated on basis of the EXW price. The margin of 18 percent shall be divided between the importer and the distributor, with 12.5 per cent and 5.5 percent, respectively.
3. The maximum limit of the retail selling price shall be calculated at 33 percent over the price by the pharmaceutical distributors.
4. Some drugs included in the list of drugs to be reimbursed by the Health Insurance Institute, upon decision of the Council of Ministers, shall be subject to differentiated margins, which shall be approved by the Council of Ministers.
5. Items 1, 2 and 3 of the Decision No. 182 of the Council of Ministers, dated 25.4.1995, "On Selling Price of Drugs/Pharmaceuticals," amended, shall be repealed.
6. The Minister of Health shall be in charge of the implementation of this decision.

This decision enters into force upon publication into the Official Journal.

**PRIME MINISTER**

**FATOS NANO**

## **DECISION**

**No. 708, DATED 16.11.2005**

### **ON SOME ADDITIONS TO DECISION NO.182 OF THE COUNCIL OF MINISTERS, “ON DRUG MARKETING PRICES,” AMENDED**

Pursuant to Article 100 of the Constitution, and of Articles 20 and 57, letter c, of the aw 9323, dated 25.11.2004, “On Drugs and Pharmaceutical Service,” upon proposal of the Minister of Health, the Council of Ministers,

DECIDED

The following additions shall be made to the Decision No. 182 of the Council of Ministers, amended:

1. Letter “c” is added in section 4.1, with the following content:

“c) for drugs which are in stock in the retail pharmacies and which are not yet equipped with the control stamp, the stamp shall include only the following data, contrary to what is provided for by letter “a” of this item:

- Title of the stamp issuing authority: National Centre for Drug Control;
- Name of retail pharmacy where such drugs are available;
- The district where the pharmacy trading such drugs is based;
- Drug price, which is filled in by the retail sellers, according to the margins approved for this purpose;

The two subsections of letter “c” may be expressed in digits, as well

.In this case, the control stamp is placed by the retail pharmacies themselves.”

2. At the end of item 4.3 shall be added the following sentences:

“For the drugs in stock at retail pharmacies, the control stamp of which shall include the data referred to in letter “c”, item 4.1., the deadline for the issuance of the quality stamp is 31 December 2005.”

This decision enters into force upon publication in the official gazette and shall be effective until 31 December 2005.

PRIME MINISTER

SALI BERISHA

**No. 504**

**COUNCIL OF MINISTERS**

**DECISION NO. 504, DATED 8.8.2007**

**ON ESTABLISHMENT AND FUNCTIONING OF DRUG PRICING COMMISSION**

Pursuant to Article 100 of the Constitution and to the Articles 50 and 51 of the Law No. 9323, dated 25.11.2004, "On Drugs and Pharmaceutical Service," amended, upon proposal of the Minister of Health and of the Minister of Finance, the Council of Minister

**D E C I D E D**

1. To establish the Drug Pricing Commission, as a permanent unit attached to the Ministry of Health.
2. The Commission shall be chaired by the Director of the Pharmaceutical Department at the Ministry of Health and shall be composed of:

-one representative of the Pharmaceutical Department at the Ministry of Health, as member; two members representatives of the Ministry of Finance,

-one member representative of the Ministry of Economy, Trade and Energy,

-two members representatives of the Health Insurance Institute

Secretary of the Commission shall be an employee of the Pharmaceutical Department at the Ministry of Health.

The heads of institutions referred to in this item shall appoint as members of the Drug Pricing Commission those employees whose functions are relevant to the function and tasks of this commission.

3. The Drug Pricing Commission shall approve each calendar year the maximum CIF price for imported drugs and manufacturing prices (in Lek) for the drugs produced in the country.

4. The manufacturers, by 31 October of each year, shall declare in writing, with an enclosed document submitted to the Pharmaceutical Department at the Ministry of Health, directly or through their office of representation in our country the CIF prices (Euro or USD) for imported drugs and the manufacturing prices for the drugs produced in the country.

The Pharmaceutical Department shall officially notify the manufacturer of the submission of information on the prices to be declared no later than two months prior to the expiration of the deadline provided for by the first paragraph of this item.

5. The Drug Pricing Commission, upon notification of the chairperson, shall convene in yearly meetings, to examine the information submitted by the secretary in compliance with items 3 and 4 of this decision and shall approve it by 5 November of each year. The Pharmaceutical Department, which approves the final drug list, shall officially notify the Customs General Directorate, the General Tax Department and the other interested institutions in regard, as well as shall publish in the Journal of Public

Announcements by 5 December of each year the drug list the approved prices on which the marketing margins shall be calculated for the successive year.

6. The Commission meeting shall be valid, when more than half of its members are present. The Pricing List of Drugs shall be approved by open vote and the decision is taken by majority of the present members. In case of parity of pros and cons, the vote of the chairman shall be determinant.

The Commission secretary prepares the meeting materials, which, upon approval by the chairman, s/he shall send to each member seven days prior to the meeting.

The Secretary of the Commission shall keep the minutes of the meeting, which shall be sent for approval to all the present members at the conclusion of the meeting or in the beginning of the successive meeting. The approved minutes shall be signed by the Commission chairman and secretary.

7. Where appropriate, the Drug Pricing Commission may convene upon request of the chairman or of at least two third of the members to examine the declared prices of the drugs registered within the calendar year. In such cases, drug prices are approved within (missing word) following the submission of the declaration at the Pharmaceutical Department.

The prices approved by the Drug Pricing Commission, in accordance with this item, shall be attached with the final drug list with the maximum CIF prices, approved according to item 5 of this decision.

Even in such case, the drug prices shall be approved in accordance with the procedures established by this decision.

8. Those drugs that are not included in the list referred to in item 5 of this decision, due to failure of declaring them by 31 October of the current year or when they are registered following this date and do not constitute the only alternative in the market, shall not be included in the list of reimbursed drugs of the successive year.

9. If the Drug Pricing Commission violates the established deadlines of approval of the list with the declared drug prices, the manufacturer shall be entitled to trade the drugs with the self-declared price.

Each decision of non-approval of the drug price in accordance with the declaration of the manufactures shall be objectively argued by the commission, supported by the reasoning based on verified criteria.

10. The manufacturer may complain against the decision of the Drug Pricing Commission within 30 days following its announcement.

11. The Commission members shall be remunerated for each meeting with 5,000 Lek (five thousand) from the approved budget funds for the Ministry of Health.

12. The Decision No. 152 of the Council of Ministers, dated 7.3.2007, "On Organization and Function of the Drug Pricing Commission" shall be repealed.

13. With the implementation of this decision shall be tasked the Ministry of Health, Ministry of Finance, Ministry of Economy, Trade and Energy and the Health Insurance Institute.

This decision enters into force upon publication in the Official Journal.

PRIME MINISTER SALI BERISHA



## **No. 910**

### **DECISION**

**No. 910, dated 18.6.2008**

### **ON APPROVAL OF PRIVATE ACTIVITY IN HEALTH SECTOR**

Pursuant to Article 100 of the Constitution, to Law No. 3766, dated 17.12.1963, "On Healthcare," amended, to Law No. 8167, dated 21.11.1996, "On Health Dentistry Service," amended, to Law No. 7975, dated 26.7.1995, "On Narcotics and Psychotropic Substances," amended, and to Law No. 9323, dated 25.11.2004, "On Drugs and Pharmaceutical Service," amended, upon proposal of the Minister of Health, the Council of Ministers

#### **DECIDED**

1. Legal and natural persons, either Albanian or foreigners, who want to exercise private activity in the health sector, shall be subject to the licensing subject.

2. The Ministry of Health shall license the following activities

a) Hospitals;

b) Manufacture of pharmaceuticals, medical devices and medical equipment;

c) Import export and marketing, wholesale or retail, of the narcotic substances and psychotropic substances.

3. Regional Public Health Departments shall issue licenses for the following activity:

a) Import-export and wholesale trading of the drugs and medical materials;

b) Establishment of medical cabinets and diagnosis centre (check-ups, consultations);

c) Establishment of medical labs (bio-chemical, microbiological, genetics labs);

ç) Establishment of dentistry cabinets (dentist, assistant dentist, dental laboratory assistant);

d) Establishment of pharmacies and pharmaceutical agencies;

dh) Disinfection services, disinfection from insects, from rats (DDT);

e) Other activities in the field of optics (optical and optometric laboratories).

4. The licensing of private activity in the field of health shall follow the self-declaration, by submitting self-declaration forms.

5. The Minister of Health shall approve the self-declaration form for each activity in the field of health.

6. The applicant subject shall submit the self-declaration form to the health institutions, in accordance with the provisions of item 2 and 3 of this decision.

7. The health institution, provided for in items 2 and 3 of this decision, within 20 days from the submission of the self-declaration form, shall carry out an inspection to verify the environmental conditions and the self-declarations made by the subject. If the inspection complies with the self-declarations of the subject, a temporary act of approval with 10 day validity is issued, until the preparation of documents that will license the activity.

8. If 20 days from the self-declaration form submission, the health institution in charge provides no answer, the activity shall be deemed as approved.

9. Decision No. 238 of the Council of Ministers, dated 10.04.2003, “On Licensing Private Activities in Health Sector”, is repealed.

This decision enters into force upon publication into the official gazette.

PRIME MINISTER

SALI BERISHA

**No. 144**

**REPUBLIC OF ALBANIA COUNCIL OF MINISTERS**

**DECISION**

**No. 144, dated 11.2.2009**

**ON APPROVING SELF-DECLARATION FORMS TO EXERCISE  
DRUG**

**WHOLESALING ACTIVITY, THEIR M G IN PHARMACIES AND  
PHARMACEUTICAL AGENCIES AND IMPORT-EXPORT**

Pursuant Article 100 of the Constitution and Articles 24, item 9, 32, item 1 i, 35, item 2 and 46, item 2, of Law 9323, dated 25.11.2004, "On Drugs and Pharmaceutical Service," amended, upon the proposal of the Minister of Health, the Council of Ministers

DECIDED

I. The approval of the self-declaration forms to exercise drug wholesaling activity, their marketing in pharmacies and pharmaceutical agencies and import-export, attached with this decision.

The Ministry of Health is tasked with the implementation of this decision

This decision enters immediately into force and is published in the Official Gazette.

PRIME MINISTER SALI BERISHA

Date

**SELF-DECLARATION**

**DRUG WHOLESALE MARKETING**

I, the undersigned, (administrator) declare to be inhabitant of at the address based on telephone no mobile and with identification document (no. of passport) technical administrator of the activity, Mr./Ms

Declare hereby under my full responsibility that

I am registered as a legal person at the National Registration Centre YES NO

I have the Registration Coupon by NRC with respective object the field of licensing application YES NO

I am not subject to any judiciary or investigation process or convicted in the field I require to exercise my activity	YES	NO
Taxation certificate for the payment of tax dues	YES	NO
Previous license	YES	NO
Hygiene-sanitary permit for the object of the activity I am going to exercise	YES	NO
[possess a membership certificate in the Order of Pharmacist, as technical administrator, issued according to my degree in pharmaceuticals and professional experience, in compliance with the law	YES	NO
Plan of the premises with a surface of over 90 m <sup>2</sup> issued by the architect/licensed engineer	YES	NO
Certificate of property or of the plan of premises issued by the architect/licensed engineer	YES	NO
Employment of technical administrator	YES	NO
The Subject complies with the "Good Drug Storage Practice", according to the applicable law	YES	NO
The Subject complies with the "Good Drug Distribution Practice", according to the applicable law	YES	NO

I hereby, declare in All responsibility, that all the above data are true and in accordance with the legislation into power.

False declaration of any of the required terms shall result into the exemption from any further procedure of the respective application.

I, hereby, declare in full responsibility that:

I am familiar with the legal and sub-legal framework of the field in which I want to exercise my activity+  
I shall meet all the requirements of the legislation into power.

**Financing and Project Agreement, on basis of Agreement dated 15.12.2004 between Government of Federal Republic of Germany and Government of Albania, KfW Frankfurt am Main (“KfW”) and Republic of Albania (“Recipient”), represented by Ministry of Finance and Ministry of Health, and Nesmark (Program-Executing Agency) for EUR 1,000,000, Family Planning III**

Article 1

Amount and Purpose of the Financial Contribution

1.1 KfW shall extend to the Recipient a financial contribution not exceeding EUR 1,000,000.-

This financial contribution shall not be repayable unless otherwise stipulated in Article 4.2.

1.2 The Recipient shall channel the financial contribution in full to the Program-Executing Agency in accordance with the conditions set forth in Article 2. The Program-Executing Agency shall use the financial contribution exclusively for financing and marketing of contraceptives as well as awareness and training measures in the family planning sector ("Program"), and primarily to pay the foreign exchange costs. The Program-Executing Agency and KfW shall determine the details of the Program and the goods and services to be financed from the financial contribution by a separate agreement.

1.3 Taxes and other public charges to be borne by the Program-Executing Agency and import duties shall not be financed from the financial contribution.

Article 2

Channelling of the Financial Contribution to the Program-Executing Agency

2.1 The Recipient shall channel the financial contribution to the Program-Executing Agency as a non-repayable grant under a separate financing agreement.

2.2 Prior to the first disbursement from the financial contribution, the Recipient shall furnish to KfW a copy and certified translation of the agreement referred to in Article 2.1.

2.3 The channelling of the financial contribution shall not constitute any liability of the Program-Executing Agency to KfW for payment obligations under this Agreement.

Article 3

Disbursement

3.1 KfW shall disburse the financial contribution in accordance with the progress of the Program and upon request of the Program-Executing Agency. By a separate agreement, the Program-Executing Agency and KfW shall determine the disbursement procedure, in particular the evidence proving that the disbursed funds are used for the stipulated purpose.

3.2 KfW shall have the right to refuse to make disbursements after 30th December 2009.

## Article 4

### Suspension of Disbursements and Repayment

#### 4.1 KfW may not suspend disbursements unless

- a) the Recipient fails to perform its obligations to KfW to make payments when due,
- b) obligations under this Agreement or under separate agreements pertinent to this Agreement have been violated,
- c) the Program-Executing Agency is unable to prove that the financial contribution has been used for the stipulated purpose, or
- d) extraordinary circumstances arise that preclude or seriously jeopardize the implementation, the operation, or the purpose of the Program.

4.2 If any of the situations specified in Article 4.1 b) or c) has occurred and has not been eliminated within a period determined by KfW, which shall, however, be at least 30 days, KfW may,

- a) in the case specified in Article 4.1 b), demand the immediate repayment of all disbursed amounts;
- b) in the case specified in Article 4.1 c), demand the immediate repayment of such amounts as the Program-Executing Agency is unable to prove to have been used for the stipulated purpose.

## Article 5

### Costs and Public Charges

5.1 Recipient shall bear all taxes and other public charges accruing outside the Federal Republic of Germany in connection with the conclusion and execution of this Agreement, as well as all transfer and conversion costs accruing in connection with the disbursement of the financial contribution.

## Article 6

### Contractual Statements and Power of representation

6.1 The Minister of Finance and such persons as designated by him or her to KfW and authorised by specimen signatures authenticated by him or her shall represent the Recipient in the execution of this Agreement other than Article 7.3 c) and 7.4, in relation to the execution of which the Minister of Health and such persons as designated by him or her to KfW and authorised by specimen signatures authenticated by him or her shall represent the Recipient. The General Director of the Program Executing Agency and such persons as designated by him or her to KfW and authorised by specimen signatures authenticated by him or her shall represent the Program-Executing Agency in the execution of this Agreement. The powers of representation shall not expire until their express revocation by the representative authorised at the time has been received by KfW.

6.2 Amendments or addenda to this Agreement and any notices and statements delivered by the contracting parties under this Agreement shall be in writing. Any such notice or statement shall have been received once it has arrived at the following address of the corresponding contracting party or at such other address of the corresponding contracting party as notified to the other

contracting party:

KfW

Postfach 11 11 41

60046 Frankfurt am Main Federal Republic of Germany Fax: +49 69 7431-2944

For the Recipient

Ministry of Finance of the Republic of Albania Bul: "Deshmoret e Kombit"

Tirana - Albania

Telefax: 00355 4 227 937

Ministry of Health of the Republic of Albania Family Planning Department

Tirana - Albania

Telefax: 00355-42-34661

For the Program

Executing Agency: NESMARK

Tirana - Albania

Telefax: 00355 4 271829

6.3 Amendments of this Agreement that affect only the legal relations between KM and the Recipient shall not require the consent of the Program-Executing Agency.

Article 7

The Program

7.1 Executing Agency

a) shall prepare, implement and operate the Program in conformity with sound financial and engineering practices and substantially in accordance with the Program conception agreed upon between the Program-Executing Agency and KfW;

b) shall award the contracts for the goods to be financed from the financial contribution upon prior international competitive bidding;



- c) shall maintain, or cause to be maintained, books and records unequivocally showing all costs of goods and services required for the Program and clearly identifying the goods and services financed from this financial contribution;
- d) shall enable the representatives of KfW at any time to inspect said books' and records and any and all other documentation relevant to the implementation of the Program, and to visit the Program and all installations related thereto and
- e) shall furnish to KfW any and all such information and records on the Program and its further progress as KfW may request.

7.2 The Program-Executing Agency and KfW shall determine the details pertinent to Article 7.1 by a separate agreement.

7.3 The Recipient and the Program-Executing Agency shall

- a) ensure the full financing of the Program and, upon request, furnish to KfW evidence proving that the costs not paid from this financial contribution are covered and
- b) of their own accord promptly inform KfW of any and all circumstances precluding or seriously jeopardizing the implementation, the operation, or the purpose of the Program.
- c) until June 2006 elaborate, coordinate and agree with KfW on a concept for the sustainable continuation of the Program areas "Selling contraceptives" and "Awareness and training measures"

7.4 The Recipient shall

- a) assist the Program-Executing Agency in conformity with sound }z. engineering and financial practices in the implementation of the Program and in the performance of the Program-Executing Agency's obligations under this Agreement and, in particular, grant the Program-Executing Agency all permissions necessary for the implementation of 'ithe Program.
- b) contribute to the financing NESMARK's of the social marketing activities starting from 2006 in an amount of not less than EUR 50,000 in total.

7.5 For the transport of the goods to be financed from the financial contribution the provisions of the Government Agreement, which are known to the Recipient, shall apply.

## Article 8

### Miscellaneous Provisions

8.1 The Recipient and the Program-Executing Agency shall ensure that the persons charged with the preparation and implementation of the Program, the award of the contract on the supplies and services to be financed and with requesting disbursements of financial contribution amounts do not demand, assume, render, grant, promise or obtain a promise of unlawful payments or other advantages in connection with these tasks.

8.2 If any of the provisions of this Agreement is invalid, all other provisions shall remain unaffected thereby. Any gap resulting therefrom shall be filled by a provision consistent with the purpose of this Agreement.

8.3 The Recipient and the Program-Executing Agency may not assign or transfer, pledge or mortgage any claims from this Agreement.

8.4 This Agreement shall be governed by the law of the Federal Republic of Germany. The place of performance shall be Frankfurt am Main.

8.5 The legal relations established by this Agreement between KfIN the Recipient and the Program-Executing Agency shall terminate with the end of the useful life of the Program but not later than fifteen years after the signing of this Agreement.

8.6 This Financing and Program Agreement shall not enter into force until the Government Agreement on which it is based has entered into force.

**No. 525**

**REPUBLIC OF ALBANIA**

**MINISTRY OF HEALTH AND ENVIRONMENT**

**Pharmaceutical Department**

**Prot. No. 525**

**REGULATION ON FUNCTIONING OF DRUG NOMENCLATURE COMMISSION**

Pursuant to Law No. 7815, "On Drugs," dated 20.04.1994, Articles 8, 12, 13, the Ministry of Health and Environment issues the "Regulation on Functioning of Drug Nomenclature Commission."

1 – The Drug Nomenclature Commission (DNC) is a consultative body of the Minister of Health and Environment and shall, therefore, be appointed by the latter.

The headquarters of this commission shall be attached to the NCDC.

2 – The commission chairman and members shall be subject to annual approval. The number is determined by the Minister of Health and Environment.

The commission shall be remunerated for the volume of its work, in accordance with the applicable legal provisions, from the revenues generated by the drug registration.

3 – The DNC chair (in the procedure of drug registration) shall take over in writing from the Drug Registration Department at NCDC the files of the drugs to be registered by the drug manufacturing companies and shall be made available for medical review and evaluation to the commission members. In the course of its course, the commission shall require, as appropriate, the opinion of experts from different fields of medicine, in accordance with the list approved by the Ministry of Health and Environment.

4 – DNC shall review and evaluate the material contained within the drug files within 50 days from the moment of submission and shall provide an opinion in writing to the DNC chairman on the respective medical opinion, supported by scientific arguments.

5 – DNC shall convene on a monthly basis or more frequently (according to the demands and needs of file evaluation) with the presence of more than 2/3 of its members and, of course, with the presence of those members who are experts of the field the particular drug is used in, coming up with the final conclusion on the files taken under examination.

The Commission shall compile the final minutes and submit it to the NCDC department (along with the respective files), which shall be further submitted to the Drug Registration Unit of this institution.

6. NCDC department shall communicate in writing the opinions and evaluations of DNC and the former shall send this information to the Pharmaceutical Department at the Ministry of Health and Environment, which starts the appropriate procedures for approval (decision-taking) by the Minister.

7 – The Minister of Health and Environment shall decide on whether a determined drug shall be registered in the Republic of Albania. Complaints on the registration procedures shall be addressed to the Minister of Health and Environment.

8 – The Drug Registration Unit at NCDC, upon a request from DNC and/or NCDC (where appropriate) shall request, when faced with insufficient documentation, that the manufacturing company submits the other relevant documents (based also on the rules and procedures of drug registration in the Republic of Albania), by submitting for further review to the interested parties.

9 – If during the post-registration period shortcomings of efficiency or effectiveness are proved in the documents declared by the company or if any irregularities is verified in the pharmaceutical aspect of the file, DNC and/or NCDC shall propose to the Minister of Health and Environment the suspension of a drug for further verification, up to the prohibition and final unregistration of the drug (if deemed appropriate).

10 – DNC, in cooperation with NCDC, HII, the Pharmaceutical Department, University Clinics of the University Hospital Centre (where appropriate) shall assist or participate in:

- Drafting the National Drug Form
- Drafting, continuous improvement of the list of reimbursed drugs
- Drafting of OTC drug list, which are sold without prescription in pharmacies
- Organization and functioning of drug vigilance, information and promotion on drugs.

11 – DNC shall review in cooperation with NCDC the documentation on the registration of drugs manufactured in the country and shall, thereafter, propose to the Minister of Health or Environment to grant or refuse the marketing permit.

12 – DNC (in cooperation with NCDC) shall propose to the Minister of Health and Environment the approval of the clinical tests on a drug by the National Ethics Committee, based also on the WHO recommendation and the experience of our clinics, and shall cooperate with this committee in order to perform clinical tests in compliance with the Good Clinical Practice.

13 – DNC shall submit to the Minister of Health and Environment an annual report in writing on the work performed by the Commission for the registration of drugs.

14 – The Regulation No. 2814, dated 1.7.1996, is repealed.

15 – This Regulation enters immediately into force.

Minister

LEONARD SOLIS

**No. 475**

**REPUBLIC OF ALBANIA**

**MINISTRY OF HEALTH**

**THE CABINET**

**ORDER No.475, dated 7.10.2004**

**ON MEDICAL PRESCRIPTION AND EXECUTION IN PHARMACIES**

Pursuant to Law No. 7815, dated 20.04.1994, "On Drugs", Law No. 7975, dated 26.07.1995, "On Narcotic Drugs and Psychotropic Substances," with the purpose of unifying prescriptions without reimbursement, issuance of prescriptions by doctors and their execution in the open pharmacies and pharmaceutical agencies, through the pharmacist assistant and doctor assistant, I

**O R D E R**

1. All graduated medical doctors, who are entitled to issue prescriptions, shall be provided with a template approved by the Ministry of Health. Issuance and execution of prescriptions out of such format shall be prohibited.
2. The open network pharmacies and pharmaceutical agencies shall be allowed to market without prescription only the drugs included in the list approved by the Minister of Health (list of drugs that may be sold without prescription in pharmacy).
3. Drugs other than those which are part of the above list may be prescribed by doctors through prescriptions with reimbursement (full or partial) or without reimbursement, according to the template.
4. Regional PHDs, Hospital Departments and RDHI are tasked to report on the annual demands for prescriptions without reimbursement to the Health Insurance Institute by 30.10.2004.
5. Upon collection of annual demands for prescriptions without reimbursement on the national scale, HII shall be tasked to their production and distribution.
6. All medical doctors are ordered to specify all the elements of the issued prescriptions, regardless of the format, by 30.11.2004.
7. Upon their execution in pharmacy, the prescriptions should be stored for the period of time provided for by the law and should be made available for purposes of control to the structures of the Ministry of health, National Centre for Drug Control and Health Insurance Institute.
8. Issue of prescriptions by medical doctors and their execution in pharmacy against this order shall make the parties subject to penalties according to the legislation into force.
9. Until the conclusion of the process (provision of medical doctors with prescriptions), HII shall not penalize the pharmacies in the course of its controls, in accordance with the provisions of the contract on the execution of prescriptions which are not in compliance with the template.

10. The Pharmaceutical Department, Hospital Department at the Ministry of Health, HII, Primary Healthcare Department (MoH), as well as the regional structures of the Ministry of Health and HII shall be in charge of taking measures for the implementation of this order.

11. This Order enters immediately into force.

MINISTER LEONARD SOLIS

**No. 256**

**REPUBLIC OF ALBANIA**

**MINISTRY OF HEALTH**

**Cabinet of Minister**

**ORDER**

**No. 256, dated 10.07.2006**

**ON IMPORT PERMITS FOR UNREGISTERED DRUGS**

**Based on Law No. 9323, dated 25.11.2004, Article 11, "On Drugs and Pharmaceutical Service," I**

**O R D E R**

1) In order to handle emergency situations (natural disasters, pandemics) or in case of demands by the health service (exclusive alternatives of drugs for in-patient and out-patient treatment), The Minister of Health shall, upon receipt of the opinion in writing by the Pharmaceutical Department at the Ministry of Health and of the National Center of Drug Control (NCDC), authorize import permits.

2) The Pharmaceutical Department, upon consulting the respective departments at the Ministry of Health, provides feedback on the needs of the services for the respective drug and its absence in the market, whereas NCDC shall verify the lack of other alternatives which are registered and present in the market.

3) This Order enters immediately into force.

**MINISTER**

**MAKSIM CIKULI**

**Nr. 1766**

**REPUBLIC OF ALBANIA**

**MINISTRY OF HEALTH**

**DIRECTORATE OF LEGAL AND LICENSING SERVICES**

**Address: Blv. "Bajram CURRI" Tirane-Albania, Tel/fax +3554 2364634 – www.moh.gov.al**

**Protocol Nr. 1766**

**Tirana, on 05.05.2008**

Mr. ARDIAN PARAVANI

NESMARK FOUNDATION

**Subject:** Response

In response of your request Nr. 20/08 date, 17.04.2007, regarding Nesmark's medical products classifications, we clarify (declare) as follows:

Products 2, 3, 4, respectively Oral contraceptives, Injecables, and Emergency Pills are drugs, while products 1, 5, 7, respectively Condoms, Pregnancy tests and IUD, are medical devices.

Thank you for your understanding,

DIRECTOR

SOKOL FRROKU



## **No. 591**

**REPUBLIC OF ALBANIA**

**MINISTRY OF HEALTH**

**THE CABINET**

**ORDER**

**No. 591, dated 30.10.2008**

### **ON APPROVAL OF REGULATION ON LICENSING PROCEDURES OF PRIVATE ACTIVITIES IN HEALTH SECTOR**

Pursuant Article 102, item 4, of the Constitution of the Republic of Albania, Decision No. 910 of the Council of Ministers, dated 18.06.2008, "On Approving Private Activity in Health Sector," in the framework of the regulatory reform to reduce barriers and facilitate the business climate, I:

#### **O R D E R**

1. To approve the regulation "On Licensing Procedures of Private Activities in Health Sector," attached with this Order.
2. The implementation of this law shall be under the responsibility of the Licensing Unit at the Law and Licensing Department at the Ministry of Health, Regional PHDs AND Tirana Regional Health Authority.
3. The Public Relation Department at the Ministry of Health shall be tasked with the publication and dissemination of this order.
4. The Information Technology Department at the Ministry of Health shall be tasked with the publication of this order on the website of the Ministry of Health.
5. This Order enters immediately into force.

**MINISTER**

**ANILA GODO**

**REGULATION**

#### **ON LICENSING PROCEDURES OF PRIVATE ACTIVITY IN HEALTH SECTOR**

This Regulation is based on Law No. 9323, dated 25.11.2004, "On Drugs and Pharmaceutical Service," amended, Law No. 9928, dated 9.06.2008, "On Stomatologic Service in the Republic of Albania," Law No. 9106, dated 17.07.2003, "On Hospital Service in the Republic of Albania," Decision No. 910 of the Council of Ministers, dated 18.06.2008, "On Approving Private Activity in Health Sector," Regulation No. 6, dated 30.11.2007, "On Hospital Waste Management."

**CHAPTER I**

**PURPOSE AND SCOPE OF REGULATION AND DEFINITIONS**

The purpose of this Regulation is to define the responsible body, procedures and criteria on licensing the private activity in the health sector for those legal and natural persons, Albanian or foreigners, who want to exercise their private activity in the field of health.

The licensing, in accordance with this regulation, shall be mandatory for any Albanian or foreigner legal and natural subject, who exercises the activity in the field of health in the Republic of Albania.

## CHAPTER II

### ORGANIZATION AND FUNCTIONING OF RESPONSIBLE LICENSING STRUCTURES

The private activity in the health sector shall be based on the applicable self-declaration principle. Self-declaration forms shall be approved by the Minister of Health.

The responsible structures to license the private activity in the health sector shall be the Ministry of Health through the Special Committee of Licenses, the regional Public Health Departments and Tirana Regional Health Authority.

#### Licensing of Private Activity by Ministry of Health

The Ministry of Health shall issue licenses for the following activities:

- Hospitals
- Manufacturing of drugs, medical equipment and devices
- Import-export and retail and wholesale marketing of narcotic drugs and psychotropic substances
- Import-export and wholesale marketing of medical drugs and devices.

The Minister of Health shall establish upon order the Special Committee of Licenses, which shall be composed of 7 (seven) members and chaired by the deputy Minister of Health.

The respective committee members may not have a working experience which is shorter than that required for the subjects.

Secretary of the Committee shall be a specialist at the Licensing Unit of Private Activity in Health Sector at the Ministry of Health.

The Committee shall convene to review applications only in the presence of no less than 4/5 of its members. The aggregate material and the minutes shall be prepared by the Licensing Unit at the Ministry.

The subject which applies to be licensed for private activity in the health sector shall fill in the self-declaration form, which has been approved in advance by the Minister of Health, and shall submit it to the Licensing Unit at the Ministry of Health.

The self-declaration form shall be available at the Licensing Unit at MoH or it may be downloaded from the website [www.moh.gov.al](http://www.moh.gov.al).

The Minister of Health shall establish upon an order the inspection group, which shall be composed of experts of the field subject to licensing, which shall perform within 20 days the inspection to verify the conditions of the environment and self-declarations made by the subject.

Upon the inspection, the performing group shall prepare the act of inspection.

If the inspection act complies with the self-declaration, a provisional act of approval shall be issued, which is valid for a 10-day period up to the finalization of the document that licenses the activity.

In the case where the responsible institution does not come up with any decision within 20 days from the date of submission, the activity shall be considered as approved.

The Act of Inspection and the self-declaration form, accompanied with the respective documentation, which have been submitted to the Licensing Unit at the Ministry of Health, shall be reviewed and approved or rejected within 30 days from the submission date of the self-declaration form by the subject to be licensed.

In case of controversial issues, the committee shall take a decision by the majority of its members.

The final license shall be signed by the Chair of the Special Committee of Licenses.

Complaints against the decision of the Special Committee of Licenses at the Ministry of Health shall be addressed to the Minister of Health, in accordance with Articles 135 and 146 of the Code of Administrative Procedures.

#### Licensing of Private Activities in Health Sector by Regional Public Health Departments and Tirana Regional Health Authority

The Minister of Health shall authorize Tirana Regional Health Authority and Regional Public Health Departments to license private activities in health sector, in accordance with DCoM No. 910, dated 18.06.2008, "On Approving Private Activity in Health Sector."

Regional Public Health Departments and Tirana Health Authority shall license the following activities:

- Medical cabinets (check-ups, consultations)
- Diagnostication centers
- Establishment of Medical Laboratories (clinical-bio-chemical, microbiological, genetic, etc)
- Establishment of dentistry cabinets (with stomatologist, assistant stomatologist, dental laboratory specialist)
- Opening of pharmacies and pharmaceutical agencies
- Disinfecting-Debugging, extermination of insects-deratation
- Activities in the optical field (optical and optometric laboratories)

Tirana Regional Health Authority (RHA) and Regional PHDs shall establish within their human and structural capacities the Special Committee of Licenses and, which is composed of 5 (five) members and is chaired by the director of the institution.

The subject, who requests licensing of private activities in the health sector, shall fill in the self-declaration form, approved in advance by the Minister of Health and shall submit it to the responsible sector authorized by Tirana RHA and Regional PHDs.

The Self-declaration Forms are available at Tirana RHA departments and regional PHDs or may be downloaded from the website [www.moh.gov.al](http://www.moh.gov.al).

The director of the institution shall establish upon an order the inspection group, which shall be composed of experts of the field subject to licensing, which shall perform within 20 days the inspection to verify the conditions of the environment and self-declarations made by the subject.

Public Health Department may request the presence of hospital specialists for the inspection. Hospital Departments shall made available experts of the fields required by PHD to the inspection group.

The directorate of National Centre for Drug Control shall sent to the Licensing Unit at the Ministry of Health, Regional PHDs and Tirana Regional Health Authority, as per the covered regions, the list with the names of pharmaceutical inspectors, who are going to inspect the private activity in the health sector.

Upon the inspection, the performing group shall prepare the act of inspection.

If the inspection act complies with the self-declaration, a provisional act of approval shall be issued, which is valid for a 10-day period up to the finalization of the document that licenses the activity.

In the case where the responsible institution does not come up with any decision within 20 days from the date of submission, the activity shall be considered as approved.

The Act of Inspection and the self-declaration form, accompanied with the respective documentation, which have been submitted to the RHA/PHD, shall be reviewed and approved or rejected within 30 days from the submission date of the self-declaration form by the subject to be licensed.

In case of controversial issues, the committee shall take a decision by the majority of its members.

The final license shall be signed by the Chair of the Special Committee of Licenses.

Complaints against the decision of the Special Committee of Licenses at the Tirana RHA and regional PHDs shall be addressed to the Minister of Health, in accordance with Articles 135 and 146 of the Code of Administrative Procedures.

Regional Public Health Departments and Tirana RHA shall submit on a quarterly basis to the Licensing Unit at the Ministry of Health electronic data on subjects licensed in their territories.

## CHAPTER III

### LICENSE TERMS AND TARIFFS

All the licenses for exercising private activities in the health sector, which are issued by the Ministry of Health, regional PHDs and Tirana Regional Health Authority shall be valid for a 5-year period, except for those fields that are otherwise regulated by legal and sub-legal acts.

The application fee of licenses for subjects who want to exercise private activities in the health sector shall be defined, per each activity, in the respective self-declaration form.

#### CHAPTER IV

#### FINAL PROVISIONS

Regulation No. 1013, dated 26.03.2003, “On Issuing Licenses for Exercise of Private Activities in Health Sector” is repealed.

**No. 682**

**REPUBLIC OF ALBANIA**

**MINISTRY OF HEALTH**

**THE MINISTER**

**O R D E R**

**No. 682, Dated 12/12/2008**

**ON DRUG IMPORT**

Pursuant to Article 102, item 4, of the Constitution of the Republic of Albania, and on Law No. 9323, dated 25.11.2004, "On Drugs and Pharmaceutical Service," amended, with the purpose to address the situation of technical problems with customs clearing of drugs at the customs point, I:

**O R D E R**

1. The National Center of Drug Control shall proceed with the previous procedures of drug import and customs clearing.
2. This procedure shall apply until the signatory of the Joint Instruction by the Ministry of Health and Ministry of Finance on the Drug Import-export Regime.
3. The Pharmaceutical Department and the National Centre of Drug Control are tasked with the implementation of this order.

This Order enters immediately into force.

MINISTER

ANILA GODO

**MOH 40**

**REPUBLIC OF ALBANIA**

**MINISTRY OF HEALTH**

**MINISTER**

**RULES AND PROCEDURES**

**No. 40, dated 26.01.2009**

**ON CRITERIA OF INCLUDING OR REMOVING DRUGS FROM REIMBURSEMENT LIST**

Pursuant to Law No. 7870 dated 13.10.1994, "On Health Insurance in the Republic of Albania," amended by Law No. 8961, dated 24.10.2002 and based on the Directive No. 716 of the Minister of Health, dated 26.12.2008, "On Drafting and Revision Commission of Reimbursed Drug List," the following rules and procedures shall be established:

I. The drugs of the reimbursement list should be registered in the Republic of Albania. In particular cases, where other alternatives are lacking, as well as based on an exhaustive argument on the necessity of use, an unregistered drug may be included in the list, with its price to be declared by the importer.

II. Inclusion or removal of a drug requires motivation, which shall be based on full arguments on whether to include the drug, mentioning its therapeutic effect, as compared to the other alternatives.

III. The decision of a drug inclusion in or removal from the List of Reimbursed Drugs shall follow the procedure below:

- a) The therapeutic category shall be determined on basis of the nozologic entity to be treated.
- b) From the therapeutic category are selected those drugs with the most favorable profile: efficiency, safety, cost.
- c) The drug is taken into consideration both as a dosage and form of dosage.
- d) When the drug is not used in the medical practice, it shall be removed from the list.
- e) When unavailable, the drug shall be neither included nor removed from the list.
- f) Priority shall be given to primary healthcare drugs.

IV. The List of Reimbursed Drugs shall be compiled on the basis of the ATC classification system, making use of the common international title (INN), commercial name, chosen pharmaceutical form, dosage, producer, price of reference and extent of coverage.

V. The Committee of the List of Reimbursed Drug shall require, where appropriate, the opinion of university clinical centres for the proposals submitted to it.

These Rules and Procedures shall enter immediately into force.

MINISTER

ANILA GODO



## MOH 73

### REGULATION

#### “ON THE REGISTRATION OF THE DRUGS IN THE REPUBLIC OF ALBANIA”

Pursuant to Law No. 9323 dated 25.11.2004 «On drugs and pharmaceutical service», Ministry of Health issues the Regulation «On the Registration of drugs in the Republic of Albania» as follows:

#### CHAPTER I

#### DOCUMENTATION FOR REGISTRATION

In order to register a drug, the interested company, through the person it authorizes, submits near the National Center of Drugs Control (NCDC) the respective file, which must contain the following documentation:

##### IA. ADMINISTRATIVE DATA

##### 7. Data on the manufacturing company:

Name..

Address..

Tel/fax

##### 8. Data on the marketing authorisation holder:

Name..

Address..

Tel/fax

##### 9. Data on the applicant for a certificate in case the applicant is different from the marketing authorisation holder

Name..

Address..

Tel/fax

##### 10. Data on the representative that is authorised by the company

Name..

Address..

Tel/fax

11. The Authorization by the company (original copy, in English)

12. Data on the distributor

Name..

Address..

Tel/fax

## IB. DATA ON THE AUTHORIZATION FOR MARKETING

B. For all the drugs

4. The certificate of pharmaceutical product issued by the respective health authority according to the WHO format (in the original copy, that is valid in the time of application)

5. The confirmation by the respective health authority that the drug is produced following the Good Manufacturing Practice -GMP ( notarized copy)

6. Copies of the registration certificates in other countries, where this drug is currently registered.

- D. B. For the products:
- i. immunosupresor
  - ii. blood and plasma products
  - iii. biotechnology derivate products

1,2,3. As above

4. The certificates of registration the drug in two countries of the European Community or in USA [in the original or copies of them (translated in English) noterised in the country of origin]

C. For the food supplements

I. The certification by the respective health authority that the product is currently in circulation in the country of origin

## IC SUMMARY OF THE PRODUCT CHARACTERISTICS

5- According to the format approved by NCDC

6- Leaflet in Albanian

7- Product in original package and reference standards for quality control, accompanied by certificate of analysis.

### 6.1.5 IV. EXPERT REPORT

I.4.1. Expert report on the chemical, pharmaceutical and biological documentation.

I.4.1.1. Product profile

I.4.1.2. Critical evaluations, signatures and data on the expert

I.4.2. Expert report on the pharmaco-toxicological documentation.

I.4.2.1. Product profile

I.4.2.2. Critical evaluations, signatures and data on the expert

I.4.3. Expert report on the clinical documentation.

I.4.3.1. Product profile

I.4.3.2. Critical evaluations, signatures and data on the expert

### 6.1.6 PART II CHEMICAL, PHARMACEUTICAL AND BIOLOGICAL DOCUMENTATION

#### I. DRUG COMPOSITION

II.1.1. Complete description and composition of the drug (name, quantity and role of the ingredients)

II.1.2. The formula used for the clinical trials

II.1.3. Pharmaceutical development

### 6.1.7

#### 6.1.8 II. DRUG MANUFACTURING METHOD

II.2.1. The formula.

II.2.2. Description of the manufacturing process and the in process controls

II.2.3. Control of the critical stages of the manufacturing process and the intermediary products

II.2.4. The validation of the manufacturing process and/or its evaluation

#### III. ACTIVE INGREDIENTS AND EXCIPIENTS

6.1.9 II.3.1 ACTIVE INGREDIENT(S)

7. II.3.1.1. GENERAL INFORMATION ON THE ACTIVE INGREDIENT(S) ( NOMENCLATURE, STRUCTURE, GENERAL DATA, CHARACTERISTICS, IMPURITIES)

II.3.1.1. Specifications

8. II.3.1.2. MANUFACTURING PROCESS OF THE ACTIVE INGREDIENTS(S)

II.3.1.2.1. Manufacturer

II.3.1.2.2. Description of the manufacturing process and the in process control

II.3.1.2.3. Validation of the manufacturing process and/or its evaluation

II.3.1.3. Control of the active ingredient(s)

II.3.1.3.1. Specifications and explanation for the specifications

II.3.1.3.2. Analytical procedure

II.3.1.3.3. Validation of the analytical procedure

II.3.1.3.3. Batch analysis (certificates of analysis)

II.3.1.4. Stability of the active component(s)

8.1.1.1

8.1.1.2 II.3.2. EXCIPIENTS

II.3.2.1. Manufacturer

II.3.2.2. Control of excipients

II.3.2.2.1. Specifications

II.3.2.2.2. Analytical procedure

II.3.2.2.3. Validation of the analytical procedures

II.3.2.3. Excipients of the animal or human origin

II.3.2.4. New excipients

8.1.2 IV. CONTROL OF THE FINAL PRODUCT

II.4.1. Product specifications

II.4.2. Analytical procedures

II.4.3. Validation of the analytical procedures

II.4.4. Batch analysis (certificates of analysis)

II.4.5. Characteristics of the related substances and impurities tests

II.4.6. Explanation about specifications

II.4.7. Primary package material test procedure

II.4.8. Primary package material closure system

### 8.1.3 V. PRODUCT STABILITY

II.5.1. Studies conducted on the final product stability

II.5.1.1. Controlled series in the packaging

II.5.1.2. Study methods

II.5.1.2.1. in the real time

II.5.1.2.2. studies in different storage conditions

II.5.1.3. Studied characteristics

II.5.1.3.1. physical characteristics

II.5.1.3.2. microbiological characteristics

II.5.1.3.3. chemical characteristics

II.5.1.3.4. packaging characteristics

II.5.1.4. Results and discussions

II.5.1.5. Conclusions

II.5.1.5.1 time definition of the drug validation

I 1.5.2. Stability studies after the first opening

### VI. BIODISPONIBILITY/ BIOEQUIVALENCE in vivo.

### 8.1.4 PART III PRE-CLINICAL DOCUMENTATION

### 8.1.5 (PHARMACO-TOXICOLOGICAL DOCUMENTATION)

### 8.1.6 I. PHARMACOLOGY

III.1.1. Primary pharmaco-dynamics

III.1.2. Secondary pharmaco-dynamics

III.1.3. Safety pharmacology

III.1.4. Pharmacodynamic interaction of the drugs

#### 8.1.7 II. PHARMACO-KYNETICS

III.2.1. Analytical method and its validation

III.2.2. Absorption

III.2.3. Distribution

III.2.4. Metabolism

III.2.5. Excretion

III.2.6. Pharmacokinetic interaction of the drugs

#### 8.1.8 III. TOXICITY

III.3.1. Toxicity of the single dosage

III.3.2. Toxicity of the repeated dosage

III.3.3. Genotoxicity

III.3.4. Carcinogenicity

III.3.5. Studies of reproduction

III.3.6. Local tolerance

III.3.7. Other toxicity studies

#### IV REFERENCE LITERATURE

#### PART IV CLINICAL DOCUMENTATION

#### 8.1.9 I. CLINICAL PHARMACOLOGY

IV.1.1. Pharmacodynamics

IV.1.2. Pharmacokinetics

#### 8.1.10 II. CLINICAL EXPERIENCE

IV.2.1. Clinical Evidence

IV.2.2. Post marketing experience (when necessary)

#### 8.1.11 III. LITERATURE OF REFERENCE

All the documentation, whose validation is the responsibility of the Manufacturing Company, must be presented in the English, Italian, French or German language

a) Tied and paged up or

b) In the electronic version (except the documents that in this regulation are foreseen to be in original or notarised)

## CHAPTER III

### ACCELERATED REGISTRATION PERIOD

1. The registration of drugs through an accelerated procedure shall be applicable only on the drugs registered with the European Medicine Evaluation Agency (EMA), the US Food and Drug Administration (FDA), in Switzerland, Canada, Australia, as well as those drugs registered in accordance with the community procedures.

2. Community procedures\* shall include:

a. the centralized procedure (EMA)

b. mutual recognition procedure

c. decentralized procedure

3. The pharmaceutical manufacturing company, through the person it has authorized, submits the respective documentation referred to in Chapter I, "Documents for Registration" at the Registration Department of NCDC, as well as declares the drug registration procedure.

3.1. The verification of the document authenticity shall be made through the requirement of original official documents or a notarised copy authenticated with the original.

3.2. Where deemed appropriate, the NCDC shall address the respective agencies with official requests of information to confirm the communitarian procedure applied to register the drug in the respective country.

4. In case the file, after the preliminary evaluation, meets the requirements of the registration regulation, the official submission of information shall take place. Submission of the documentation shall be accompanied with the application form.

Following the completion of the application form, the subject shall pay in advance the fees established by the respective decision.

5. The acceptance date of the file for purpose of registration shall be the date of confirmation by NCDCD that the subject made the payment at the bank.

\*<http://www.ema.europa.eu/index/authorisation.htm>;

[http://ec.europa.eu/enterprise/pharmaceuticals/procedure/procedures\\_en.html](http://ec.europa.eu/enterprise/pharmaceuticals/procedure/procedures_en.html)

6. Upon submission of the documentation referred to above, NCDC shall examine the documents within a period of 20 business days and shall submit it to NDC for approval.

7. NDC shall examine the respective file within five days upon receipt of the notification in writing by NCDC, and, if the documentation is complete, it issues the recommendation for registration. In the case

of incomplete documentation, NDC shall notify accordingly in writing the respective pharmaceutical company.

8. NCDC, based on the NDC recommendation, shall draft the proposal for the registration of the respective drug, which is submitted for approval to the Minister of Health.

9. Upon receipt of the registration order by the Minister of Health, NCDC shall send to the respective company an official notification on the drug registration and payment of the respective registration fee.

10. The fee shall be paid no later than 2 months upon receipt of the notification.

11. Within 15 days from the bank confirmation of the payment of the respective fee, NCDC shall issue to the respective company the Registration certificate on each dosage form of the registered drug, which shall be valid for a five-year period from the date of issue of the order by the Minister of Health.

12. The company shall have no rights of import until the moment of issuance of the registration certificate.

13. In the case where the company has failed to pay the respective registration fee following two months upon receipt of the notification, NCDC shall write within 15 days the drug unregistration proposal, which is submitted to the Minister of Health for approval.

14. In order to re-register the drug, the interested company should apply at NCDC from 5-3 months prior to the expiration of the previous registration.

15. If no application is submitted up to the expiration of the drug registration, a new application should be submitted for registration.

16. If the product will no longer be marketed, the company should notify NCDC two months prior to such termination, providing the relevant motives.

17. If the re-registration application is submitted later than 5 – 3 months prior to the expiration of the deadline, a fee on the delay shall be applied. NCDC shall preserve the right to respond within a five-month period from the submission of the application.

18. For each alteration the drug is subjected to during the five-year period of registration, the company should submit a variation application, according to the respective regulation of variations.

19. Where deemed appropriate, in order to complete the examination related to an application, NCDC may request the applicant to perform an inspection (verification of the manufacturing process and conditions) in the manufacturing plant. Such inspection may also be performed without prior office. This inspection should take place within the time limits of the answer.

## Annex I

### On the food supplements

Point 5 of the registration procedure is as follows:

Within 3 months from the submission date, the NCDC performs the examination of the documentation, and in case:



A. The documentation fulfills the requirements of the respective regulation the NCDC prepares the proposal for the respective drug registration which is then passed for approval to the Minister of Health.

For the medical plant products for human use

#### POINT 5 OF THE REGISTRATION PROCEDURE IS AS FOLLOWS

Within 4 months from the submission date the NCDC examines the documentation and in case:

A. The documentation fulfills the requirements of the respective regulation the NCDC prepares the proposal for the respective drug registration which is then passed for approval to the Minister of Health.

For the OTC drugs

A.

Chapter I

Part I

Part II

They are the same as the “Drugs Registration Regulation”

Part III

References from literature

Part IV

References and efficiency (For the new formulations), based on the literature and on the clinical studies.

B.

Point 5 of Chapter II “Registration procedure” is as follows

Within 4 months from the submission date, the NCDC examines the documentation and in case:

a. The documentation fulfills the requirements of the respective regulation the NCDC prepares the proposal for the respective drug registration which is then passed for approval to the Minister of Health.

C.

Advertisements for the drugs of this category are allowed only through prior approval by NCDC.

e. The advertisement must not be addressed to children

f. The advertisements can state that a drug can cure, prevent or relieves a symptom only if this is proved.

g. The advertisement must inform for the respective limits of the drug use when it is considered necessary

h. The advertisements are allowed only for the registered drugs of this category

For the generic drugs, whose alternative is not registered for the first time in Albania

Point 5 of the registration procedure states as follows

Within 6 months from the submission date the NCDC examines the documentation and in case:

A. The documentation fulfills the requirements of the respective regulation it prepares the proposal for the registration of the respective drug which is then passed for approval to the Minister of Health.

#### Annex II

A). For the cases given below the generic drugs are considered to be equivalent without the need of the equivalence studies documentations:

a) the preparations administered in parenteral way (e.g. the intravenous, intramuscular, subcutaneous or intrathecal way) as watery solutions that contain the same active substances, in the same concentrations and the same excipients in comparable concentrations;

b) solutions for oral use that contain active substances with the same concentration and that do not contain an excipient that is known or for which there is the doubt to reach the gastrointestinal route (transit) or the absorption of the active substance;

c) gases;

d) powdery substances for re-construction as a solution that meets the criteria a) or b) above;

e) the preparations for the ears or the eyes prepared as water solutions that contain the same active substances with the same concentrations and essentially the same excipients in comparable concentrations;

f) topical preparations prepared as water solutions that contain the same active substances in the same concentrations and essentially the same excipients in comparable concentrations;

g) inhaling or aerosol nasal preparations that are administered with or without the same equipment (appliance, mechanism); they are prepared as watery solutions and contain the same active substances in the same concentrations and essentially the same excipients in comparable concentrations. The special proof in vitro shall be required to be documented in comparison with the mechanism with which is prepared the inhaling preparation.

h) the product in examination changes from the referring product only in the dosage of the active substance that it contains with the condition to fulfill all the following requirements:

i. pharmaco-kynetics is linear

ii. the qualitative composition is the same

iii. the rapport between the active substance and the excipient is the same (or in the case of the small dosages of the drug) the rapport between the excipient is the same.

iv. the two products are manufactured by the same manufacturer in the same production place

- v. it must be conducted a bioequivalence study in the original product
- vi. the speed of dissolution is the same for the two products in the same proof conditions.

Regarding requirements (e), (f) and (g) given above, it is the task of the applicant to demonstrate that the excipients in the generic drugs are essentially the same, and are present in the concentrations which are comparable to the reference product (market leader). If this information for the reference product can not be ensured by the applicant, and no such data are presented to the authorities, studies in vivo must be conducted.

B) When it is necessary the documentation of the equivalence studies:

Test form/ dosage is a watery solution, or steril powdery substance that is prepared (re-constituted) before the administration, for parenteral use, but that changes from the reference form/ dosage regarding the quantity (the concentration) of the active substance(s) and with different qualities from the reference ones.

b) Test form/ dosage is a non-watery solution, for parenteral use, but that changes from the reference form/ dosage regarding the quantity (the concentration) of the active substance(s) and/or contain(s) excipients with different qualities from the reference ones.

c) Test form/ dosage is a watery solution, suspension or a powdery substance that is prepared (reconstituted) before the administration, for oral use (with systemic effect), but that changes from the reference form/ dosage regarding the quantity (the concentration) of the active substance(s) and/or contains excipients in a quantity and quality that is different from the reference ones, for which there are no documented data that can prove that the excipients do not modify the absorption of the substance and/or the gastrointestinal transit.

d) Test form/ dosage is a tablet or a capsule for oral use (with systemic effect).

e) Test form/ dosage is not used with parenteral routes, and oral routes, but with systemic effect, (patch for the skin or mucus, suppository, etc.)

f) Test form/ dosage is a fixed combination with systemic effects.

g) Test form/ dosage is a watery solution for local use, non systemic (oral, nasal, ocular, dermal, rectal, vaginal), but that changes from the reference form/ dosage regarding the quantity (concentration) of the active substance(s) and the quality of the excipients.

h) The non-solution Test form/ dosage is destined to local use, non-systemic (oral, nasal ocular, rectal dermale, vaginal.)

Regarding points **a)** up to **g)** the bioequivalence studies (the comparable biodisposition), when possible, are sufficient to prove the therapeutical equivalence, the efficiency and the safety, otherwise the pharmacodynamic and/or clinical comparable studies are necessary.

Regarding point **h)** the therapeutical equivalence must be proved through clinical or pharmacodynamic comparable studies.

## REGULATION FOR THE FOOD SUPPLEMENTS REGISTRATION

Point I

This regulation shall be implemented for the food supplements which are introduced and marketed as alimentary products.

These products can be traded only if packed primarily.

#### Point 2

c. "Food supplement" are those products that are a plus to the normal diet and that make up a concentrated alimentary substances source or other substances that have an alimentary or physiological effect, be that separate substances or mixed with other substances, in defined and marketable dosages i.e. capsules, tablets, pills, etc, powdery substances in packets, solutions in ampouls, medicine bottles or in-drops medicine bottles, or other similar liquids and powdery substances which are predefined to be taken in small dosages.

d. The food supplements are the following substances:

- Vitamins
- Minerals
- Aminoacids
- Other substances with a special alimentary value

c. The food supplements that are used for special alimentary purposes are:

c1. The food supplements that because of their specific composition or their specific method of production, are easily distinguished by the food used for normal consumption, that are appropriate for the alimentary values they have and that are marketed in such a way so that to show this appropriateness.

c2. A special alimentary use must fulfill specific alimentary requirements

- regarding certain categories of people who have problems with the digesting process or their metabolism, or
- regarding specific categories of people who are in special physiological conditions and as a consequence are in a situation where they can gain from the controlled consumption of certain substances, from the components of the food supplements or
- the new-born babies or the children in a good health

#### Point 3

5. Only the vitamins and the minerals included in List I, in the form defined in List II can be used in the production of the food supplements.

6. The substances defined in Annex I are excluded from the food supplements.

7. The purity requirements of the products are in accordance with the pre-defined normatives of the European Community.

8. The food supplements can contain substances that are not included in Lists I and II only in the cases when the substance is used in one or more food supplements that circulate in two or more EU countries.

#### Point 4

1- The maximum quantitative levels of the vitamins and minerals that are found in the food supplements in every daily dosage recommended by the producer must be defined taking into account:

c. The allowable levels of vitamins and minerals that result from the widely known scientific studies, taking into consideration the different sensitivity levels regarding different categories of consumers.

d. The level of their consumption by the normal food diet

2- The reference values of vitamins and minerals for the population must also be taken into account.

8- In order to guarantee that the food supplements contain a considerable quantity of vitamins and minerals, it is necessary that the manufacturer defines a minimum level of the recommended daily dosage.

#### Point 5

1- Labeling, the introduction in the market and the advertisements must not attribute therapeutical qualities to the food supplements or must not qualify them as being able to prevent or to cure diseases and not even to refer to such capacities.

2- It is obligatory that the label of the food supplements must contain the following elements:

f. The name of the category of the alimentary substances or other substances that characterise the product or a relative explanation regarding the nature of these substances.

g. The daily dosage recommended for the product.

h. A warning for not exceeding the daily dosages

i. The indication that the food supplements can not be taken as substitute for a complex diet.

j. The indication that the products should be kept away from children.

#### Point 6

The labeling and the publicity of the food supplements must not contain direct sentences or sentences that imply that in general an equilibrated and complex diet is not able to ensure the food supplements in sufficient and appropriate quantities.

#### Point 7

The quantity of the alimentary substances or of the other substances that have alimentary or physiological effect that are ingredients of the product must be numerically expressed in the label of the product.

#### Point 8

The applicable specific quantities of the food groups for specific alimentary use foreseen in point I shall be defined through this regulation.

- a. The essential requirement regarding the nature and the composition of the products
- b. Requirements that are linked to the quality of the raw material
- c. Requirements regarding hygiene
- d. The list of the supplement substances
- e. Requirements that are linked to the packaging, the introduction and the warnings
- f. Samples and the methods of analysis

#### Point 9

The application for the registration of the food supplements must contain:

##### I – Administrative data

- e. Data on the manufacturing company ( name, address, telephone, fax, fiscal code)
- f. Data on the importing company (distributors)
- g. name, address and the authorization (in original) of the person that shall follow the registration procedures.
- h. The evidence of the registration fee payment

##### II – Data on the marketing authorization

- e. A document from the Ministry of Health or the respective state institution that proves that the product is allowed to be sold in the country of origin
- f. A document that proves that the product is currently in the market in the country of origin.
- g. GMP of the manufacturing company.
- h. The registration certificate or a certificate that enables the sale of this product in other countries.

#### 8.1.12 III – SUMMARY OF THE PRODUCT CHARACTERISTICS

1. A summary of the product characteristics that is approved by the respective authority in the country of origin
2. Packed preparation (original sample) accompanied by the respective certificates of analysis
3. Packaging and label in the English and Albanian language.
4. Leaflet paper in the Albanian language.
5. Data on the packaging method, and the package sample.

### 8.1.13 IV - DRUG COMPOSITION

Full description and composition of the drug (name, quantity and the role of the ingredients)

8.1.14 THE NATIONAL CENTRE OF THE DRUGS CONTROL CAN ASK FOR OTHER TECHNICAL DOCUMENTATIONS REGARDING THE FOOD SUPPLEMENTS. THE DATA ON THE FOOD SUPPLEMENTS PUBLISHED IN THE SCIENTIFIC LITERATURE INTERNATIONALLY KNOWN CAN BE CONSIDERED AS AN EVIDENCE.

### ANNEX I

The food groups that are used for special alimentary purposes

- 1- Formulations for new-born babies
- 2- Milk or other food (follow up)
- 3- Food for children
- 4- Food with low energetic value or reduced in order to be used for weight control
- 5- Diet food that are used for specific medical purposes
- 6- Food with low salt quantity, where are also included the dietary salt with a low quantity or no presence at all of sodium.
- 7- Food with no gluten
- 8- Food that is used in the cases of the intensive muscular strain, especially for the sport people
- 9- Food used by people that suffer from carbohydrates metabolism disorders

### LIST I

### 9. VITAMINS AND MINERALS USED IN THE MANUFACTURING OF THE FOOD SUPPLEMENTS

3. Vitamins	4. Minerals
Vitamin A	Calcium
Vitamin D	Magnesium
Vitamin E	Iron
Vitamin K	Copper
Vitamin B1	Iodine
Vitamin B2	Zinc

Niacin	Manganese
Pantotenic Acid panthotenic	Sodium
	Potassium
VITAMIN B6	Selenium
Folic acid	Chromium
Vitamin B12	Molybdenum
Biotine	Fluorine
Vitamin C	Chlorine
	Phosphorus

## LIST II

### 10. VITAMIN SUBSTANCES AND THE MINERALS THAT ARE ALLOWED FOR THE PRODUCTION OF THE FOOD SUPPLEMENTS

#### REGULATION ON HERBAL MEDICINAL PRODUCTS FOR HUMAN USE

##### Point 1

This regulation shall be implemented for herbal medicinal products which meet all the following criteria:

- (f) those that have indicators especially appropriate to the traditional medical plant products, which because of their composition and their purpose of use, are foreseen and defined to be used without the control of a medical professional; for conducting diagnosis, for description or monitoring of the treatment;
- (g) they must be for administration under a specific dosage and a specific way of use;
- (h) they are oral preparations, for external use and/or for inhalation;
- (i) the traditional consumption period is completed (30 years)
- (j) the data for the traditional use of the medical product are sufficient; in particular the product proves to be unharmed in special conditions of use and the pharmacological effects or the efficiency of the medical product is trustful based on experience and on the long time of use.

##### Point 2

This regulation shall be applied:

4-For the traditional medical plant products.



5-For traditional not-plant substances which are used in products that have medical use such as

-Fish oils

-Bee milk or other insects products

Bacterial products such as acidophilus/ acidobifidus/lactobacillus and other bacterial products.

-Other

6-For the combinations of traditional plant substances or the combinations of non-plant traditional substances as well as the use of other non-plant and not traditional substances [e.g. vitamins/minerals which go under the dosage that defines them as medical products and are subject to the pharmaceutical legislation], in the cases when the main active ingredient of this product is a traditional plant product or a traditional non-plant product.

### Point 3

This regulation shall not be applied:

5. This regulation shall not be applied for any plant or non-plant medical product that should be authorized according to the Regulation of the Medical Products or the Poisons (According to what the law defines regarding the poisons)

6. This regulation is not applied for the products that contain one or more vitaminous substances, or minerals or combinations of one or some of these substances.

The presence of vitamins or minerals in the medical plant product (for which there exist full and documented evidence) does not give the product the right to be registered as food supplement, on condition that the action of vitamins and mineral is dependent on the action of the active plant ingredients related to the specific stated indication.

7. Although, in the cases when the competent authorities decide that a traditional medical plant product fulfills the criteria for the authorization in compliance with the regulation of food supplements, the dispositions of this chapter shall not be applied.

8. This regulation shall not be applied for the medical homeopathic products.

### Point 4

It shall be considered:

A- Traditional medical plant product

The term 'traditional' defines a product used in the European Community during the whole period of 30 years that is prior to the application date. The requirement that the drug must be used during all this period is fulfilled even when the drug marketing is not based on a specific authorization. This requirement is widely met when the number and the quantity of the ingredients of the medical product is lowered during the period mentioned in this article.

As an alternative to prove the use of the product during the 30 year period of time in EU countries, the applicant must bring an evidence of the product use in a period of 30 years, in:

- (iii) A specified territory or territories outside the Community, or
- (iv) Partially in one or some countries of the Community and partially in such specified territories, if during this period the product has not been circulating within the Community for at least 15 years.

**B- Medical plant product:**

every medical product that has in its content as active ingredients only one or more plant preparations that are combined with one or more such plant preparations;

**D- Plant substances/preparations:**

Mainly all the unbroken (untouched), fragmented, or cut, plant parts, alga, mushrooms, lichens in a non-processed form and usually dry but sometimes fresh. Some eksudate which do not undergo a special treatment are also considered plant substances. The plant substances are defined exactly from the part of the plant used and the botanic name in accordance with the binominal system (gen,species,variety and the author)

**E-Herbal preparations**

The preparation gained from placing the plant substances under such treatments as:

extracting, distillation, fractioning, purification, concentration or fermentation. These include crumbled or powdered plant substances, tinctures, extracts, essential oils, processed liquids and eksudate.

**Point 5**

2.The application for registration of a traditional medical plant product shall be rejected if one of the following conditions is fulfilled:

- 9. The product does not meet the requirements of this regulation,
  - 10. The qualitative and quantitative composition is not as stated,
  - 11. The proposed indications do not meet the requirements of this regulation,
  - 12. The product can be harmful in normal conditions of use,
  - 13. The information for the traditional use is insufficient especially when the pharmacological effects or the efficiency are not convincing regarding the long- term use and the experience,
  - 14. The product is classified as a medical product as an object of the medical description,
  - 15. The product is not an oral preparation, for external use or for inhalation
  - 16. The pharmaceutical quality is not demonstrated in a sufficient way.
2. NCDC shall notify officially the candidate for the rejection reasons.

**Point 6**

2. Every label and leaflet in the packaging shall include a statement also for the effect that:

(c) The product is a traditional medical plant product for being used in specific indication(s), based only on the long-term use, and

(d) If the symptoms continue during the use of the medical product or if undesired effects occur that are not mentioned in the packaging instruction paper, the user should consult a doctor or a qualified practitioner for medical care.

#### Point 7

The advertisement of the traditional medical products registered according to this Regulation, must meet the requirements for the drugs advertising.

In the advertising of a traditional medical product registered according to this Regulation must be included also:

a). The product is a traditional medical product used for a specified indication, the efficiency of this product is based only on a long-term use.

b). The user must consult a doctor or another qualified person if the symptoms persist during the use of this product

#### Point 8

The application for the registration of the medical plant products for human use should contain:

2. Every application for registration must contain:

(i) Administrative data [name of the product, composition, manufacturer etc],

(ii) Summary of the Product Characteristics [SPC],

(iii) Data regarding any authorization or registration to market the product, that are provided by the applicant from the EU member countries or the third-world countries, as well as decisions for rejection, cancelling or revoking the registration authorization and the reasons for these decisions (if there are any),

(iv) Manufacturing or distribution licence of the applicant,

[Every person that produces a traditional medical product registered according to this Regulation should keep a manufacturing licence issued by the Competent Authority pursuant to the national legislation.]

(v) Copies of the proposed label and patient paper,

(vi) Bibliographical evidence of the effects that this product or a similar product that is connected with this one that has been used in EU countries, during all the period of at least 30 years before the application date.

(vii) A full file on quality.

(viii) A bibliographical summary of the safety data. For the combined products these data should have to do with the specific combination that is used ; the data should have to do only with the active substances, when these are not known sufficiently.

(ix) Evidence in supporting the traditional status of the product and the traditional proposed use

(x) The expert report that gives in detail, explains, justifies and assesses the information that is submitted and presented in points (vi)-(ix) above.

#### Point 9

The registration of a product according to this regulation can be cancelled or revoked when.

3. The applicant does not fulfill the registration requirements,

4. New data on safety throw light on a potential threat on the public health in case this drug is used.

### 11. VARIATIONS TO THE TERMS OF REGISTERED MEDICINAL PRODUCTS

1.1. Minor variations (type I) are all variations listed in Annex 2 to this Procedure.

1.2. Major variations (type II) are all variations not listed in Annexes 2 and 3 to this procedure, including Urgent Safety Restrictions

1.3. Variations to the terms of medicinal products registered in Albania must be registered. Type I and II variations are registered by the National Center of Drugs Control.

1.4. If variations listed in Annex 3 to this Procedure are proposed to a registered medicinal product, a new application for a marketing authorisation must be submitted and it shall be examined by the NCDC pursuant to clause 3 of this Procedure.

1.5. If manufacturer proposes a type II variation, an application in standard format (Annex 1) together with the supplementary documentation must be submitted to the NCDC and an assessment fee of 100 €, in case of new indications from the same therapeutic area assessment fee of 100 €, has to be paid.

Within sixty days after the receipt of the application, the NCDC has the right to request that the applicant for the marketing authorisation submit supplementary documentation. The applicant shall be notified in written form of the registration or rejection of the variation applied for.

1.6. If manufacturer proposes a type I variation, an application in standard format (Annex 1) must be submitted to the NCDC and an assessment fee of 50 €, has to be paid.

If, within thirty days after the date of submission of the application, the NCDC has not sent to the applicant a written notification stating the grounds for refusing registration of the variation or requesting submission of additional information, the variation is deemed registered.

1.7. In the case of type I and II variations, an application for a variation shall not concern more than one variation. Where several variations are proposed, a separate application must be submitted in respect of each variation sought.

1.8. If a proprietary medicinal product is authorised in the EU pursuant to the centralised procedure, all the decisions of the European Commission concerning variations to the proprietary medicinal product (including decisions which reject a variation) must be submitted in the NCDC.

1.9. After a preliminary assessment of an application for a variation, the NCDC has the right to request that the applicant supply additional information (depending on the character of the proposed variation).

1.10. Upon a negative answer from the NCDC, a marketing authorisation holder may, within thirty days, amend the application in accordance with the requirements of the NCDC. If the marketing authorisation holder does not amend the application within thirty days, the application is deemed rejected.

1.11. Where a variation requires consequential updating of the summary of product characteristics, labelling or package leaflet, the time period for implementing the consequential update must be agreed with the NCDC.

## 2. SUSPENSION AND REVOCATION OF MARKETING AUTHORISATION

2.1. The NCDC may suspend a marketing authorisation upon failure to guarantee the availability of the medicinal product, or infringement of the marketing procedure for medicinal products.

2.2. Upon suspension of a marketing authorisation, the import of the medicinal product into Albania and its marketing to wholesalers and pharmacists is prohibited until the removal of the reasons for the suspension.

2.3. A marketing authorisation is revoked on a manufacturer's application or if:

a) The marketing authorisation holder has, in violation of the provided procedure, made changes in the composition, packaging or labelling of the registered medicinal product which are misleading concerning the current use of the medicinal product or hazardous the life of the patient;

b) The procedure for advertising medicinal products is violated;

c) The manufacturer does not, upon a request by the NCDC, supply additional information concerning the safety of the proprietary medicinal product;

d) The medicinal product is recognized as having become hazardous for its user.

2.4. Revocation of a marketing authorisation is in the competence of the Ministry of Health, based on the propose of the NCDC. After the removal of the reasons, which resulted in the revocation of a marketing authorisation, a new application for a marketing authorisation may be submitted in NCDC.

2.5. Upon revocation of a marketing authorisation, the manufacturer must collect the medicinal product marketed in Albania from wholesalers, pharmacists and hospitals.

### Annex I: APPLICATION FOR REGISTRATION OF VARIATIONS

#### APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION

Authorized in EU _____	National authorization _____
Type I _____	Urgent safety restriction (Type II) _____
Type II _____	Annual variation for human influenza vaccines (Type II) _____

(Please tick the appropriate category of the variation)

Product name: _____	Name and address of MA holder: _____
---------------------	--------------------------------------

Active substance(s)/quantitative	_____
_____	_____
Pharmaceutical form:	Representative: _____
_____	_____
Date of issue of marketing authorization:	Telephone number: _____
_____	Fax number: _____
Number of marketing authorization:	_____
_____	
Date of last renewal of marketing authorization:	
_____	

Prepayment \_\_\_\_\_ €,

(According to the provision of the Law "On Drugs" No. 9323, date 25.11.2004 Item 3 and on the basis of the Order by the Minister of health No. 327 date 14.07.05 The fee of the Bank Commission should be paid by you.)

The address is:

National Centre of Drug Control

Raiffeisen Bank - ALBANIA

Accounting No. 4302/000/00

Confirmation for prepayment .....

Date.....

Vladimir MARGJEKA

DIRECTOR

Annex 2

MINOR VARIATION (TYPE I)

12. Change in the name and/or address of the marketing authorization holder

13. Change in the name of the medicinal product

14. Change in the name of the active substance

15. Change in the name and/or address of a manufacturer of the active substance where no Ph.Eur.Certificate of Suitability is available.

16. Change in the name and/or address of manufacturer of the finished product.

The manufacturer should be the same.

17. Change in ATC code

Medicinal product for human use

18. Replacement or addition of a manufacturing site for part or all the manufacturing process of the finished product

a. Secondary packaging site for all types of pharmaceutical forms

b. Primary packaging site

1. Solid pharmaceutical forms, e.g tablets and capsules

2. Semi-solid or liquid pharmaceutical forms

3. Liquid pharmaceutical forms

c. All other manufacturing operations except batch release

19. Change to batch release arrangements and quality control testing of the finished product

a. Replacement or addition of a site where batch control/testing takes place

b. Replacement or addition of a manufacturer responsible for batch release

1. Not including batch control/testing

2. Including batch control/testing

20. Deletion of any manufacturing site (including for an active substance, intermediate or finished product, manufacturer responsible for batch release, site where batch control takes place)

21. Minor change in the manufacturing process of the active substance

22. Change in batch size of active substance or intermediate

a. Up to 10-fold compared to the original batch size approved at the grant of the marketing authorization

b. Downscaling

c. More than 10-fold compared to the original batch size approved at the grant of the marketing authorization

12. Change in the specification of an active substance or a starting material/intermediate, or reagent used in the manufacturing process of the active substance

c. Tightening of specification limit

d. Addition of a new test parameter of the specification of

1. An active substance
2. starting material/intermediate/reagent used in the manufacturing process of the active substance
3. Change in test procedure for active substance or starting material, intermediate or reagent used in the manufacturing process of the active substance
  - c. Minor change to approved test procedure
  - d. Other changes to a test procedure, including replacement or addition of a test procedure
32. Change in the manufacturer of the active substance or starting material/reagent/intermediate in the manufacturing process of the active substance where no Ph. Eur. Certificate of Suitability is available
  - a. Change in the site of the already approved manufacturer (replacement or addition)
  - b. New manufacturer (replacement or addition)
33. Submission of a new or updated Ph. Eur. Certificate of Suitability for an active substance or starting material/reagent/intermediate in the manufacturing process of the active substance
  - a. From a manufacturer currently approved
  - b. From a new manufacturer (replacement or addition)
1. Sterile substance
2. Other substances
34. Change in
  - a. The re-test period of the active substance
  - b. The storage conditions for the active substance
35. Replacement of an excipient with a comparable excipient
36. Change in specification of an excipient
  - a. Tightening of specification limits
  - b. Addition of a new test parameter to the specification
37. Change in test procedure for an excipient
  - a. Minor change to an approved test procedure (in registration)
  - b. Major change to an approved test procedure for a biological excipient
  - c. Other changes to a test procedure, including replacement of an approved test procedure by a new test procedure
38. Submission of a new or updated Ph. Eur. Certificate of Suitability for an excipient



- a. From a manufacturer currently approved
  - b. From a new manufacturer(replacement or addition)
    - 1. Sterile substance
    - 2. Other substances
39. Change in source of an excipient or reagent from a TSE risk to a vegetable or synthetic material
- a. Excipient or reagent used in manufacture of biological active substance or manufacture of a finished product containing biological active substance
  - b. Other cases
40. Change in synthesis or recovery of a non-pharmacopoeial excipient (when described in the dossier)
41. Change to comply with the Ph.Eur. or with the national pharmacopoeia of a Member State
- a. Change of specification(s) of a former non-European pharmacopoeial substance to comply with Ph. Eur. Or with the national pharmacopoeia of a Member State
    - 1. Active substance
    - 2. Excipient
42. Change in the specification of the immediate packaging of the finished product
- a. Tightening of specification
  - b. Addition of a new test parameter
43. Change to a test procedure of the immediate packaging of the finished product
- a. Minor change to an approved test procedure
  - b. Other changes to a test procedure, including replacement or addition of a test procedure
44. Change in any part of the packaging material not in contact with the finished product formulation
45. Change in the qualitative and/or quantitative composition of the immediate packaging material
- a. Semi-solid and liquid pharmaceutical forms
  - b. All other pharmaceutical forms
46. Change (replacement, addition or deletion) in supplier of packaging components or devices (when mentioned in the dossier ), spacer devices for metered dose inhalers are excluded
- a. Deletion of a supplier
  - b. Replacement or addition of a supplier

- 47. Change to in-process tests or limits applied during the manufacture of the product
  - a. Tightening of in process limits
  - b. Addition of new test and limits
- 48. Change in batch size of the finished product
  - a. Up to 10-fold compared to the original batch size approved at the grant of the marketing authorization
  - b. Downscaling down to 10-fold
  - c. Other situation
- 49. Minor change in the manufacture of the finished product
- 33. Change in the coloring system of the flavoring system currently used in the finished product
  - A. Reduction or deletion of one or more components of the
    - 1. Coloring system
    - 2. Flavouring system
  - b. Increase, addition or replacement of one or more components of
    - 1. Coloring system
    - 2. Flavouring system
- 33. Change in coating weight of tablets or change in weight of capsule shell
  - a. Immediate release oral pharmaceutical forms
  - b. Gastro-resistant, modified or prolonged release pharmaceutical forms
- 36. Change in shape or dimensions of the container or closure
  - a. Sterile pharmaceutical forms and biological medicinal products
  - b. Other pharmaceutical forms
- 37. Change in the specification of the finished product
  - a. Tightening of specification limits
  - b. Addition of a new test parameter
- 36. Change in the test procedure of the finished product
  - d. Minor change to an approved test procedure

- e. Minor change to an approved test procedure for biological active substance or biological excipient
  - f. Other changes to a test procedure, including replacement or addition of a test procedure
37. Change or addition of imprints, bossing or other markings (except scoring/break lines) on tablets or printing on capsules, including replacement, or addition of inks used for product marking
38. Change of dimensions of tablets, capsules, suppositories or pessaries without change in qualitative or quantitative composition and mean mass
- c. Gastro-resistant, modified or prolonged release pharmaceutical forms and scored tablets
  - d. All other tablets, capsules, suppositories and pessaries
39. Change in pack size of the finished product
- b. Change in the number of units (e.g. tablets, ampoules, etc.) in a pack
    - 1. Change within the range of the currently approved pack sizes
    - 2. Change outside the range of the currently approved pack sizes
  - b. Change in the fill-weight/fill volume of non-parenteral multi-dose products
40. Change in:
- b. The shelf life of the finished product
    - 1. As packaged for sale
    - 2. After the first opening
    - 3. After dilution or reconstitution
  - b. The storage conditions of the finished product or the diluted/reconstituted product
41. Addition, replacement or deletion of a measuring or administration device not being an integrated part of the primary packaging
- c. Addition or replacement
  - d. Deletion

### Annex 3

#### VARIATIONS TO THE TERMS OF REGISTERED MEDICINAL PRODUCTS REQUIRING SUBMISSION OF NEW REGISTRATION APPLICATIONS

- I. Changes to the active substances
  - I.1. Addition of one or more active substance(s) including antigenic components for vaccines.
  - I.2. Deletion of one or more active substance(s) including antigenic components for vaccines.

- I.3. Quantitative change to the active substance (change in the level of active substance).
- I.4. Replacement of the active substance by a different salt/ester complex/derivative.
- I.5. Replacement of the active substance by a different isomer, a different mixture of isomers, of a mixture by an isolated isomer (e.g. racemate by a single enantiomer).
- I.6. Replacement of a biological substance or product of biotechnology with one of a different molecular structure; modification of the vector used to produce the antigen/source material.
- I.7. A new ligand for a radiopharmaceutical.
- 2. Changes to the therapeutic indications
  - 2.1. Addition of an indication in a different therapeutic area, for either treatment, diagnosis or prophylaxis.
  - 2.2. Change of the indication to a different therapeutic area (for treatment, diagnosis or prophylaxis).
- 3. Changes to strength, pharmaceutical form and route of administration
  - 3.1. Change of bioavailability.
  - 3.2. Change of pharmacokinetics, e.g. change in rate of release of active substance.
  - 3.3. Addition of a new strength.
  - 3.4. Change or addition of a new pharmaceutical form.
  - 3.6. Addition of a new route of administration.

#### 11.1.1 APPLICATION FOR THE RENEWAL OF MARKETING AUTHORIZATION

Instruction for the applicant

Following the implementation of Law No. 9323 dated 25.11.2004 “On drugs”, Ministry of Health issues the regulation “On the re-registration of drugs in the Republic of Albania”

#### 11.1.2 CHAPTER I

#### 11.1.3 DOCUMENTATION TO BE SUBMITTED FOR THE RE-REGISTRATION PROCEDURE

In order to re-register the drug the interested company, through the authorized person, submits near the registration department of the NCDC the file which should contain the following documentation.

#### I. Administrative data

#### I. Data on the manufacturing company

Name..

Address..

Tel/Fax

2. Data on the authorization marketing holder

Name..

Address..

Tel/Fax

3. Data on the applicant regarding the certificate if different from license holder

Name..

Address..

Tel/Fax

4.Data on the person who is authorized from the company.

Name..

Address..

Tel/Fax

5. The authorization from the company

6. Data on the distribution

Name..

Address..

Tel/Fax

7. Official statement of the sale price (CIF) of the drug by the Manufacturing Company, with which the drug is going to be sold in Albania at least for one year period. For any change the company should inform the pharmacy directorate in the Ministry of Health.

8.The copy of the payment should be in conformity with the Order of the Minister of Health

II Summary of the file

III Data for authorizing the launching of the drug in the market

E. For all drugs

I.Certificate of the pharmaceutical product issued from the proper health authority according to WHO application.(in original, valid in the time of application)

2. Confirmation from the manufacturing company that the drug is manufactured according to GMP.

3. Copy of the registration certificate in other countries where this drug is actually registered.

F. For product. i. immunosuppressor

ii. blood and plasma products

iii. biotechnology derivative product

1,2,3. As above

4. Registration certificate in two countries of European Community or USA (original or notary copy, translated in English, in the country of origin)

C. Integrator

I. Certificate from the proper health authority that the drug is actually in circulation in the country of origin.

IV Drug information

1- Summary of the product characteristic (according to application approved by NCDC)

2- Patient information leaflet in Albania.

3- Samples of the finished product (two) accompanied by its certificates of analyses.

V Declaration on variations during of 5 years of drug marketing and the list of these variations. A copy of the approval of these variations.

VI Information for the primary and secondary package.

VII Short summary product characteristic for chemical, pharmaceutical and biological documentation.

VIII Periodic safety update rapport

## CHAPTER II

### 1.1.1.4 THE RE-REGISTRATION PROCEDURE

#### General data

4. Re-registration is the procedure after the expiring date of the validation of the Registration Certificate in the Republic of Albania. 5 years after marketing of medicines all companies should prolongate the Registration of their medicines.

5. In the period of 3-5 months before the end of the drug registration, The National Center for Drug Control (NCDC), admits written authorization from the Pharmaceutical Company about their interest in the drug re-registration.

6. If the preliminary verification notices that

a) Documentation is not full, application will be refused

b) Documentation is according to the regulation, the application form is filled in and this accompanies the submission of the documentation near the NCDC

4. The date of application for registration renewal is the date in which the application for registration is signed by the director.

5. If the application for the re-registration is submitted later than 5 to 3 months before of the registration time (5 years), a fee for the delay shall be applied. NCDC conserves the right to give the response to the company within a period of 5 months from the date of the application is signed.

6. The NCDC conserves the right to request supply the documentation from the company If there are remarks regarding the content of the documentation or other information on the drugs is needed. In this case the renewal of the registration will be after 5 months from the date of the representation of the documentation to the NCDC.

7. If there is no application for the re-registration until the end of the period of registration it is necessary to be prepared a new application for the registration

8. The prolongation of the medicines is valid for 5 years.

9. The payment for each drug (dosage/form) that is registered should be done in conformity with the Order of Minister on the re-registration fee and should be paid before submitting the documentation.

10. The Minister of Health, based on the proposal, issues the drug re-registration order, on which base the NCDC issues the respective certificate for the drug re-registration for another 5-year period.

Leonard SOLIS

MINISTER





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